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ACTA REUMA. PORT., XVI (3): 111-113, 1991

EDITORIAL

LOMBALGIAS

Vale Mais Prevenir do que Remediar!

M. VIANA DE QUEIROZ*

As lombalgias são dores lombares crónicas acompanhadas ou não de bloqueio variável, sem radiculalgia clinicamente patente.

A etiologia mais frequente das lombalgias antes dos 45 anos de idade é a traumática, e depois desta idade a degenerescência discal, em cerca de 95% dos casos. Os restantes 5% são preenchidos pelas lombalgias inflamatórias infecciosas, metabólicas, tumorais e outras.

A prevalência das dores lombares crónicas na população em geral varia entre os 10% e os 45% conforme os Autores, sendo a sua incidência também na população em geral da ordem dos 5% a 10% conforme as séries. São mais frequentes na idade média da vida, e afectam igualmente os dois sexos até aos 60 anos de idade. Depois deste grupo etário parecem ser mais frequentes no sexo feminino.

Não respeitam etnias sendo as raças branca, negra e amarela igualmente atingidas.

50% dos episódios duram menos de uma semana, e 90% menos de um mês.

Nos Estados Unidos são a primeira causa de limitação da actividade antes dos 45 anos, e a terceira causa entre os 45 e os 64 anos de idade. Ainda neste

* Chefe de Serviço de Reumatologia do H.S. Maria. Professor Associado de Reumatologia da Faculdade de Medicina de Lisboa.

país são a segunda causa de consulta em clínica geral, e a primeira causa de consulta em reumatologia.

Os factores de risco das lombalgias são controversos, sendo a altura superior a 180 cm no homem e a 170 cm na mulher; a diminuição da força dos músculos abdominais e dorsais; as alterações da estática do ráquis; as malformações ao nível da charneira lombo-sagrada; a gravidez; os traumatismos; a condução automóvel; os desportos violentos e/ou competitivos, e os factores psicológicos (ansiedade, depressão, etc.) os mais comuns na população em geral.

Entre os factores de risco relacionados com a actividade profissional destacam-se os trabalhos pesados; a elevação de cargas; as posturas prolongadas em ortoestatismo ou na posição sentada; os movimentos frequentes de flexão e de torsão do ráquis e a exposição a vibrações (condutores, agricultores, etc.).

Uma regra de memorização fácil, a regra dos cinco, diz-nos que 1/5 da população sofre de lombalgias; 1/5 dos lombálgicos consulta o clínico geral; 1/5 destes doentes observados pelo clínico geral é enviado ao especialista; 1/5 dos doentes vistos pelo especialista é hospitalizado e, finalmente, 1/5 dos doentes hospitalizados é operado.

O custo económico das lombalgias é enorme.

Desconhecemos os números envolvidos no nosso país (pensamos que não estão contabilizados), mas nos Estados Unidos da América do Norte são superiores a 20 biliões de dólares, e em França são da ordem dos 8 milhões de francos. Neste país, e no que concerne à medicina privada, as lombalgias são responsáveis por 2,5% dos medicamentos prescritos; 8% dos exames radiológicos solicitados, e 30% da actividade dos fisioterapeutas.

Face a todos estes números afigura-se-nos ser mais fácil prevenir do que remediar as lombalgias.

A prevenção deve fundamentar-se em estudos epidemiológicos e de biomecânica do ráquis, de modo à coluna vertebral ser utilizada de uma maneira equilibrada e "económica".

Para ser eficaz a prevenção das lombalgias deve contemplar acções de formação do bom uso do ráquis; contemplar todas as actividades ao longo das 24 horas do dia (as 6 ou 8 horas de repouso nocturno em cama e postura correctas são primordiais); e ter uma duração prolongada.

Não é possível concretizar e levar a bom porto uma "política" de prevenção em geral, ou das lombalgias em particular, sem sensibilizar grupos alvos tão importantes como os médicos e os paramédicos, os professores, as crianças e os pais das crianças em idade escolar, os empresários e empregadores, os fabricantes de mobiliário; os professores de educação física e os treinadores e, ainda, os políticos, os sindicatos; as seguradoras, os organismos privados e do Estado e, finalmente, mas não menos importante, o grande público.

As lombalgias podem e devem ser prevenidas nas empresas, na escola, em casa, no escritório, no manejo de cargas, nos transportes e no desporto.

Nas empresas são indispensáveis a adaptação do posto de trabalho e do equipamento ao trabalhador e não deste ao trabalho, bem assim outras medidas ergonómicas de que se destaca a remoção de barreiras arquitectónicas. Muito importantes e já postas em prática no Japão e nos Estados Unidos, são os tempos livres no trabalho e as escolas de dorso. As escolas de dorso, as

"Back Sckool" dos autores anglosaxónicos tem por objectivo ensinar a pequenos grupos, com a ajuda de médicos, cinesiterapeutas, ergoterapeutas, psicólogos, etc, a anatomia funcional e a biomecânica do ráquis, bem assim as actividades profissionais e de lazer.

Na escola é fundamental a correcção dos defeitos posturais e gestuais das crianças, bem como a correcção das alterações da estática. De grande relevância é o mobiliário quase sempre desadaptado.

Em casa para além do mobiliário e das posturas, é de grande interesse, tal como nas empresas, o manejo correcto de cargas, que deve ser feito com o dorso erecto, os joelhos flectidos, evitando a torsão do ráquis (o "pivot" devem ser os pés), e aproximando-as o máximo do tórax.

Finalmente no que diz respeito ao desporto, sobretudo ao de fim de semana, hoje em dia tão comum, é importante aprender a técnica de execução correcta das diferentes actividades desportivas, treinar regularmente, evitar os desportos violentos e ou competitivos, e não ultrapassar as capacidades fisiológicas do indivíduo.

"Last but not the least", nenhum plano de prevenção deve esquecer a avaliação; só assim é possível detectar erros e proceder à sua correcção e, por outro lado, só assim a sociedade pode reconhecer a importância da prevenção.

ACTA REUMA. PORT., XVI (3): 115-123, 1991

O TRATAMENTO CIRÚRGICO DA ARTRITE REUMATÓIDE
Estudo de 493 doentes

FERNANDO SARAIVA*, ARMANDO MALCATA**, J.C. ROMEU**
E M. VIANA DE QUEIROZ***

RESUMO

No sentido de determinar a prevalência da cirurgia ortopédica ou neuro-cirúrgica nos doentes com artrite reumatóide, efectuou-se um estudo retrospectivo interessando uma população de 493 indivíduos com esta conectivite. Destes, 55 (11.2%) tinham sido submetidos a algum tipo de cirurgia ortopédica ou neuro-cirúrgica, num total de 106 intervenções. Os tempos médicos de duração da artrite reumatóide e das queixas da área intervencionada até à cirurgia foram, respectivamente, de 12.24 ± 1.37 e 7.96 ± 1.08 (SEM) anos. O tempo médio de evolução da artrite reumatóide após a cirurgia foi de 4.24 ± 0.49 anos. As articulações mais frequentemente intervencionadas foram as coxo-femurais (29; 27.4%), os joelhos (15; 14.2%) e as metatarso-falângicas (14; 13.2%), sendo os tendões e suas baínhas nas mãos e punhos (18; 17%) e o canal cárpico (9; 8.5%), as estruturas mais frequentemente intervencionadas ao nível das partes moles. As técnicas cirúrgicas mais vezes efectuadas foram a artroplastia total da coxo-femural (25; 23.6%), a ressecção das cabeças metatársicas (12; 11.3%) e a tenossinovectomia dos extensores da mão (1; 9.4%). Seis doentes foram submetidos a cirurgias de revisão, num total de 8 intervenções (7.5% de todas as cirurgias). Comparando a idade média, a distribuição por sexo, a presença de factores reumatóides IgM no soro e a duração da

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artrite reumatóide, entre os dois grupos de doentes, com e sem cirugia, só no último parâmetro referido se detectou uma diferença estatisticamente significatica [I (-4.16) < 0.0002], sendo a duração da doença maior no grupo submetido a cirurgia.

ABSTRACT

The authors have determined the timing and the details of the recourse to surgery in a cohort of 493 non-selected cases or rheumatoid arthritis. This was necessary in 11.2% of the patients after a mean follow-up period of 12.24 ± 1.37 years. Total hip arthroplasty, resection of metatarsal heads and tenosinovectomy of hand extensors were the surgical procedures more often performed. Comparing the two groups of patients with and without surgery, the duration of disease, more protracted in the former group, was the only parameter in which a significative statistical difference was found.

INTRODUÇÃO

Alguns autores (1,2) consideram ter sido o desenvolvimento do conceito de substituição articular total, a partir de Charnley (3), a contribuição isolada mais importante para o tratamento dos reumatismos. De facto, o tratamento da artrite reumatóide (AR), o paradigma da conectivite destrutiva a nível articular, é essencialmente médico, assentando num trabalho de equipa sob a coordenação do reumatologista (4). Infelizmente, ou porque a terapêutica é instituída tardiamente, ou porque a doença se mostra particularmente agressiva, é preciso recorrer à cirurgia para diminuir a dor e/ou restituir a função. Ao conceder estes benefícios a cirurgia melhora a qualidade de vida do doente e, quando permite posologias medicamentosas mais ligeiras, minora a iatrogenia (5). Favorece também, a comunidade, ao reduzir as necessidades de adaptação ao domicílio (no que isso implica de investimento em meios físicos e humanos) e a premência da institucionalização em geral, ditadas pela perda das capacidades indispensáveis à autonomia (1,6).

Segundo Mowat (2), até 10% dos doentes das consultas de reumatologia são submetidos a cirurgia ortopédica em cada ano. Allander (7) em 293 doentes com AR, encontrou indicação para cirurgia reconstrutiva "major" em 8% dos casos, enquanto 30% colheriam benefícios funcionais de intervenções "minor". Num estudo de Kahn (8), de um universo de 288 doentes não seleccionados com AR, 32% foram submetidos a cirurgia ortopédica.

Os objectivos do presente estudo retrospectivo foram os seguintes: determinar, numa população não seleccionada de doentes com AR a prevalência do acto cirúrgico especializado, ortopédico ou neuro-cirúrgico, desde que directamente imposto pela conectivite; traçar o perfil clínico e demográfico da referida população, e compará-lo com o dos doentes não submetidos a cirurgia.

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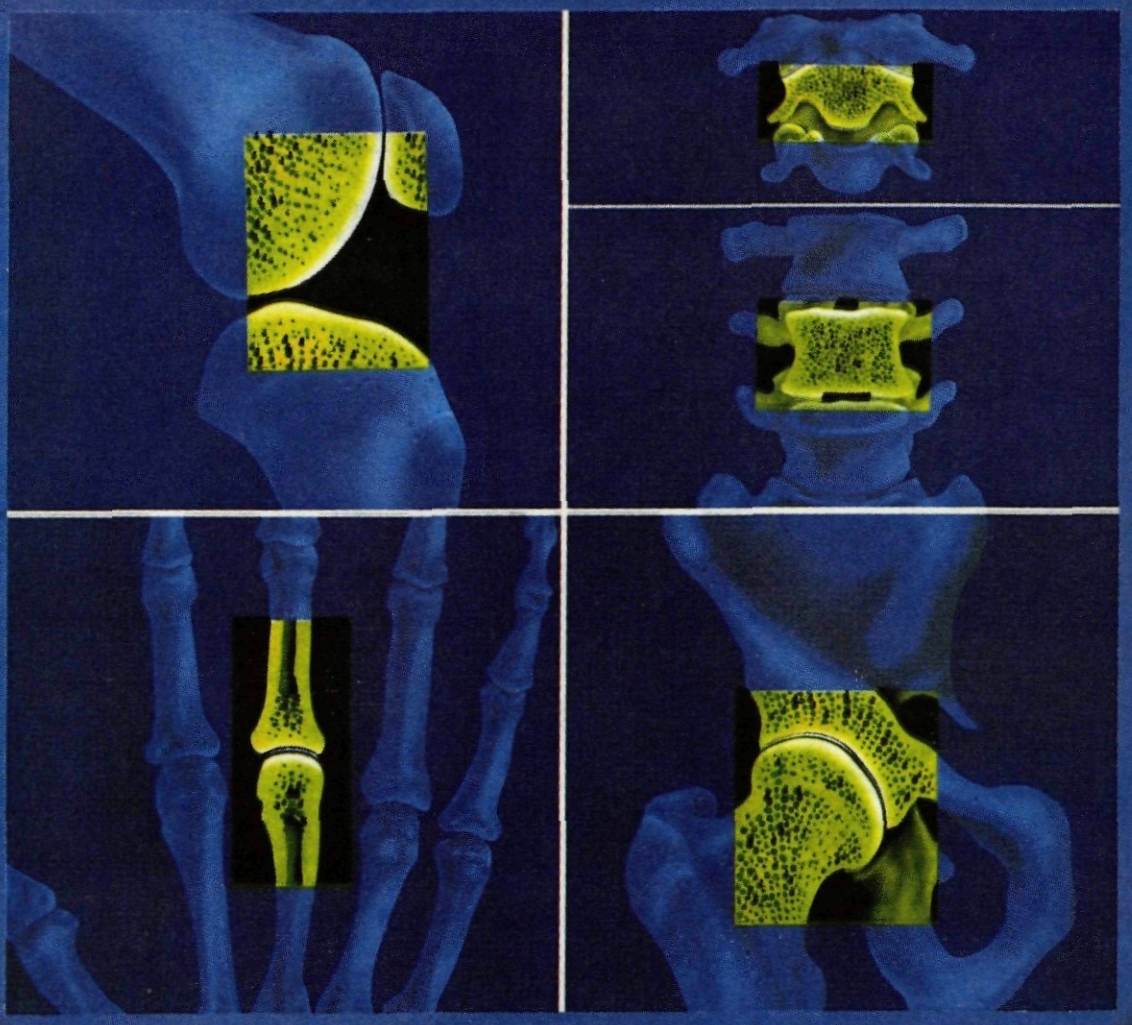

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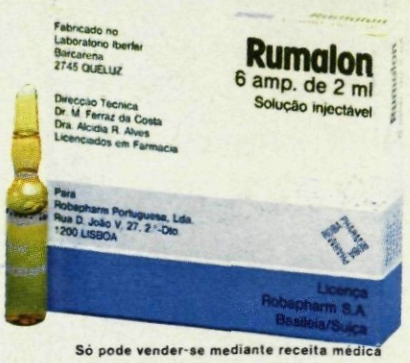

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MATERIAL E MÉTODOS

Foram revistos os processos de 493 doentes com AR clássica ou definida, segundo os critérios de ARA (9), seguidos na Consulta de Reumatologia do Hospital de Santa Maria. Para cada doente valorizámos a idade, o sexo, a presença ou ausência de factores reumatóides IgM no soro, o tempo de duração da AR até 31 de Dezembro de 1989 e, no caso dos doentes em que foi praticado algum acto cirúrgico ortopédico, registámos também: o tempo decorrido desde o início das queixas locais até à intervenção; a evolução da AR até à referida cirurgia e desta até à supracitada data.

Foram excluídas 6 cirurgias, interessando 5 doentes, por não terem relação directa com a AR: destas, uma osteossíntese do joelho, de causa traumática e uma artrodese da coxo-femural, após artrite específica, foram realizadas antes do início da conectivite; as restantes, efectuaram-se após a instalação desta, sendo três (duas osteossínteses e uma artroplastia total, por fractura pós-traumática) ao nível do cólo do fémur, e outra para correcção de canal lombar estreito.

Para o tratamento estatístico dos resultados utilizámos o teste do chi-quadrado nas variáveis nominais e o teste z nas variáveis numéricas. Foram considerados significativos os valores de $p < 0.05$.

RESULTADOS

Do universo de 493 doentes, 55 (11.2%) tinham sido submetidos a algum tipo de cirurgia ortopédica ou neuro-cirúrgica, num total de 106 intervenções. Destas, 77 (72.6%) foram cirurgias osteo-articulares e 29 (27.4%) cirurgias das partes moles. A idade média dos doentes operados era de 50.7 ± 11.2 anos. Quarenta e três (78.2%) eram do sexo feminino e 12 (21.8%) do sexo masculino. Trinta e seis doentes (65.5%) eram sero-positivos para os factores reumatóides IgM no soro, e 16 (29.1%) sero-negativos. Em 3 doentes (5.4%) não encontrámos registos referentes a este parâmetro.

A duração média da AR nos doentes operados, no final do estudo, era de 17.06 ± 11.21 anos.

Os tempos médios de evolução, em termos de cronologia comparativa, tendo como referência a altura da cirurgia, estão registados no Quadro I.

No Quadro II revela-se a distribuição das cirurgias pelos doentes. Na sua maioria estes foram submetidos a uma ou duas intervenções, mas mais de metade das cirurgias foram efectuadas em doentes que já tinham sido operados anteriormente uma ou duas vezes. O número médio de cirurgias por doente foi de 1.93.

Nos Quadros III e IV estão discriminadas as intervenções realizadas.

As articulações mais frequentemente submetidas a cirurgia foram as coxo-femurais (29; 27.4%), os joelhos (15; 14.2%) e as metatarso-falângicas (14; 13.2%). Ao nível das partes moles as intervenções mais comuns foram as das mãos e dos punhos, interessando, nomeadamente, os tendões e suas baínhas (18; 17%) e o canal cárpico (9; 8.5%).

QUADRO I

Tempos médios de evolução em relação à cirurgia

	tempo (anos ± SEM)
Evolução da AR até à cirurgia	12.24 ± 1.37
Evolução das queixas locais até à cirurgia	7.96 ± 1.08
Evolução da AR após a cirurgia	4.24 ± 0.49

QUADRO II

Distribuição das cirurgias pelos doentes

n.º de cirurgias/doente	n.º de doentes	total de cirurgias
1	22	22 (20.8%)
2	19	38 (35.8%)
3	11	33 (31.1%)
4	2	8 (7.5%)
5	1	5 (4.7%)

As técnicas mais frequentemente efectuadas foram a artroplastia total da coxo-femural (25; 23.6%), a ressecção das cabeças metatársicas (12; 11.3%) e a tenossinovectomia dos extensores da mão (10; 9.4%).

Seis doentes foram sujeitos a cirurgias de revisão, dois deles por duas vezes (re-revisão de sinovectomia do joelho e de descompressão do nervo mediano), totalizando assim 8 operações (7.5% de todas as cirurgias). No Quadro V discriminam-se os dados concernentes a estas intervenções.

No Quadro VI comparam-se os doentes com e sem cirurgia. Dos parâmetros avaliados, o único em que a diferença assumiu um valor estatisticamente significativo foi a duração da AR, superior no grupo com cirurgia.

DISCUSSÃO

Um número significativo de doentes reumatóides beneficia de actos cirúrgicos, geralmente do foro ortopédico, directamente impostos pela conectivite. No nosso estudo a percentagem de doentes intervencionados (11.2%), é significativamente inferior ao valor médio de aproximadamente 30% relatado por outros autores (7,8). Por outro lado, enquanto os nossos doentes foram submetidos a

QUADRO III

Cirurgias osteo-articulares (n = 77)

localização	Cirurgia	n.º (%)
Coxo-femural		29 (27.4)
	artroplastia total	25
	artrodese	2
	osteotomia de varização	1
	sinovectomia	1
Joelho		15 (14.2)
	artroplastia total	5
	sinovectomia	5
	artrodese	3
	osteotomia de valgização	1
	osteotomia de varização	1
Metatarso-falângicas		14 (13.2)
	ressecção das cabeças metatársicas	12
	correcção de hallux-valgus	2
Punho	artrodese	5 (4.7)
Tíbio-társica	artrodese	4 (3.8)
C1-C2	artrodese	4 (3.8)
Ombro	artrodese	1 (0.9)
Cotovelo	artrodese	1 (0.9)
Metacarpo-falângicas	artroplastia total	1 (0.9)
Dedos das mãos	correcção de deform. em botoeira	1 (0.9)
Sub-astragalina	artrodese	1 (0.9)
Médio-társica	artrodese	1 (0.9)

1.93 cirurgias em média, no estudo de Kahn (8), o único que conhecemos da literatura com as características do nosso, o número médio de cirurgias por doente foi de 2.5. Estas discrepância poderá ter, teoricamente, uma das seguintes três explicações: os nossos doentes têm uma doença menos agressiva ou respondendo melhor à terapêutica médica, não evoluindo, assim, tão frequentemente para situações extremas de dor e incapacidade que suscitem a indicação cirúrgica; os nossos reumatologistas não contemplam tão frequentemente a solução cirúrgica; os ortopedistas com quem trabalhamos, assoberbados pela traumatologia e limitados pela escassez de meios, não conseguem dar resposta atempada aos doentes que lhes são propostos. Dado que não se conhecem variações geográficas ou étnicas que apoiem a primeira hipótese, pensamos que a diferença de prevalência apontada estará entre as duas últimas.

Kahn (8) comparando os doentes com e sem cirurgia detectou que os

QUADRO IV

Cirurgias das partes moles (n = 29)

localização	Cirurgia	n.º (%)
Extensores da mão		13 (12.3)
	tenossinovectomia	10
	tenorrafia e/ou transposição	3
Canal cárpico	descompressão do mediano	9 (8.5)
Tendões não especificados da mão		4 (3.8)
	tenossinovectomia	2
	tenorrafia e/ou transposição	2
Região popliteia	quistectomia de Baker	2 (1.9)
Flexores da mão	tenossinovectomia	1 (0.9)

QUADRO V

Cirurgias de revisão

local.	cir. inicial	cir. revisão	tempo após cir. ant.
C-F	sinovectomia	artrop. total	2.5 anos
C-F	artrop. total	artrop. total	16 anos
C-F	artrop. total	artrop. total	1 ano
C1-C2	artrodese	artrodese	1 ano
CnCa	descompressão	descompressão	6 meses
CnCa	descompressão	descompressão	1.2 anos
J	sinovectomia	sinovectomia	2 anos
J	sinovectomia	artrodese	1 ano

Legenda: C-F-coxo-femural; C1-C2-atloido-odontoideia; CnCa-canal cárpico; J-joelho

primeiros eram significativamente mais idosos, apresentavam doença de maior duração, e tinham mais frequentemente factores reumatóides IgM no soro. No nosso estudo e comparando os mesmos parâmetros só encontrámos uma diferença estatisticamente significativa no que concerne à duração da AR, a qual se mostrou mais prolongada no grupo intervencionado. Este resultado comum aos dois estudos não surpreende dado que ocorrendo há mais tempo, é compreensível que a sinovite tenha acabado por ser mais destrutiva e incapacitante, com o consequente recurso à cirurgia.

QUADRO VI

Comparação dos doentes com e sem cirurgia

	AR s/cir. (n=438)	AR c/cir. (n=55)	Sign. Estat.
Idade média (anos)	52.8±12.25	50.7±11.2	NS
Sexo (♀/%;♂/%)	344/78.5;94/21.5	43/78.2;12/21.8	NS
Duração da AR (anos)	10.47±9.83	17.06±11.21	1-I (4.16)<0.0002
F.R.IgM (+/%;-/%)	308/73.5;111/26.5	36/69.2;16/30.8	NS

Comparando ainda os nossos resultados com os de Kahn (8) podemos dizer que ambos coincidem quanto às estruturas mais intervencionadas e quanto às técnicas mais utilizadas. Salienta-se no entanto a maior expressão das artroplastias totais no estudo de Kahn (8) (36.5% das cirurgias), comparativamente com o nosso (29.2% das cirurgias), sendo esta diferença particularmente significativa no que respeita à artroplastia total do joelho (10.4% e 4.7%, respectivamente).

Dado que o nosso trabalho foi retrospectivo, não nos foi possível apreciar com rigor o benefício que a cirurgia proporcionou. Todavia, das técnicas efectuadas pelo menos cinco vezes ficou-se a impressão de que as artroplastias do joelho e da anca, as tenossinovectomias da mão e a ressecção das cabeças metatársicas foram as intervenções mais bem sucedidas.

Reportando-nos aos resultados da literatura referentes a algumas das técnicas mais frequentemente efectuadas, salientamos taxas de bons resultados, da ordem dos 95%, para a artroplastia total da anca (10,11,12), 80% para a artroplastia total do joelho (13), e 70% a 95% para as tenossinovectomias das mãos e punhos (14,15). Relatadas como proporcionando uma significativa maioria de resultados gratificantes são também a ressecção das cabeças metatársicas (16,17,18), a artrodese do punho (19) e a descompressão do nervo mediano ao nível do canal cárpico (20). Já no que concerne à sinovectomia cirúrgica do joelho, embora existam relatos de bons resultados com esta técnica, nomeadamente no que respeita à eliminação da dor e da tumefacção, eles são temporários e não se acompanham de benefício equivalente no que concerne à melhoria funcional (21,22). Desta forma e segundo Gschwend (23), a indicação para sinovectomia cirúrgica do joelho só deverá ser posta em casos seleccionados que apresentem sinovite proliferativa exuberante ou produção macissa de fibrina.

Pensamos que o contributo da cirurgia ortopédica para a melhoria da qualidade de vida dos doentes não pode ser subestimado. Julgamos que a realização de mais estudos prospectivos a longo prazo, designadamente com os materiais e técnicas mais recentes será necessária para que a importância daquela contribuição possa ser melhor avaliada.

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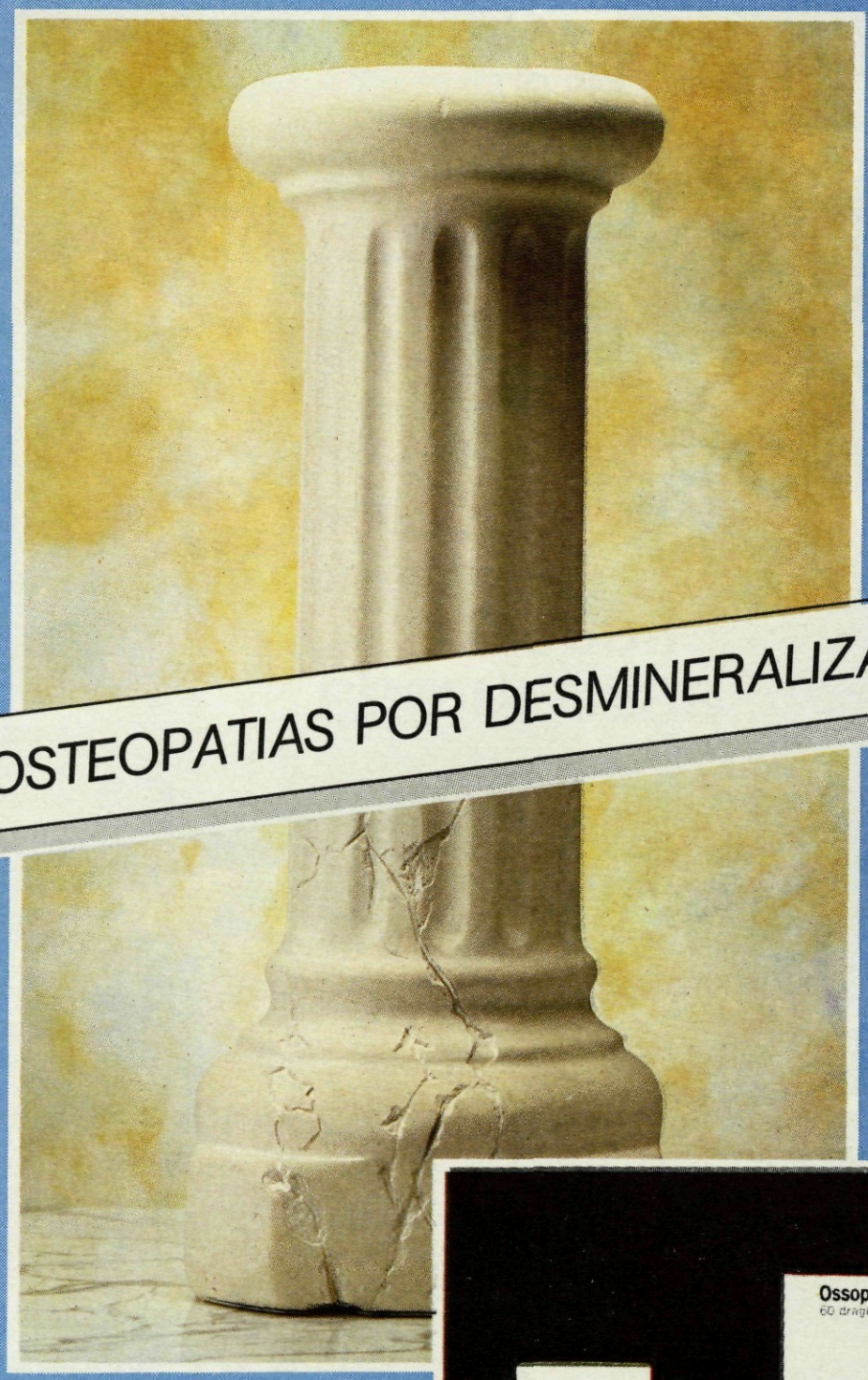

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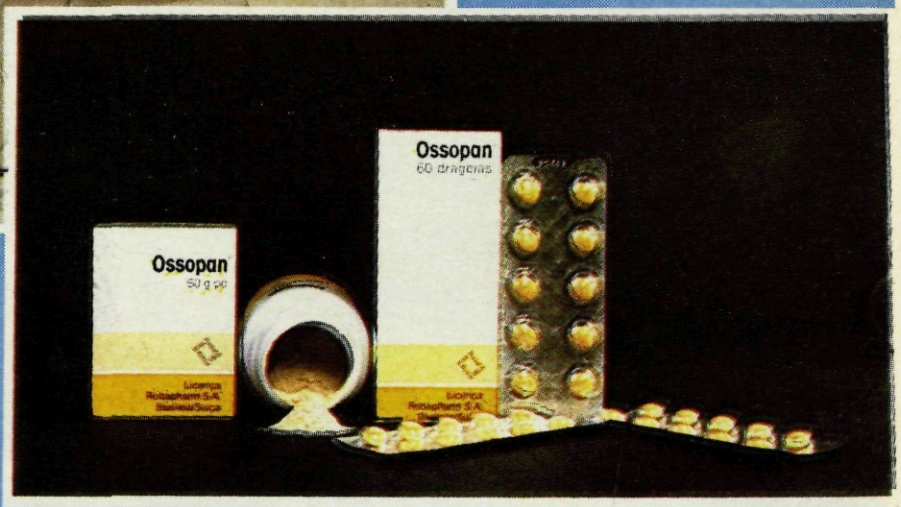

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EUROPEAN RESEARCH ON INCAPACITATING DISEASES AND SOCIAL SUPPORT (EURIDISS)

Part I: Rheumatoid arthritis

CHAPTER ONE: RATIONALE OF THE EURIDISS-PROJECT*

I INTRODUCTION

The increase of chronically ill patients has an enormous impact on the health care institutions and on public health policy, besides the significant influences chronic diseases have on the quality of life of the individual patients and other people closely related to him. This development has led to a growing interest in the management of chronic diseases on an individual level and on a state level. It has become evident that the organization and functioning of the health care system is related to the role of the informal care system (or social network) in taking care of the chronically ill. There is also empirical evidence, that the informal care system may affect the course of the chronic disease together with the formal (professional) care system. It is unknown however what the several formal care systems exactly contribute to the course of chronic disease and how they interact with the informal care system in the managing of chronic diseases. International comparison is needed to reveal the specific role of the several formal care systems and their interaction with the informal care system.

The objective of this study is to understand the role of the informal and formal care system in managing chronic, incapaciting diseases and how both systems (formal and informal) affect the course of the chronic disease process. Chronic diseases affect the physical and social functioning of the patient (qua-

* European Research on Incapacitating Diseases and Social Support
Groningen/Nancy/Reims — 1989

lity of life) and have an impact on the health care and social security system. The study will describe how people cope with their incapacitating disease and will test the role of the formal and informal care system on the physical and social functioning of the patient. The formal and informal care system may play an important social supportive role. Social support has been reported as being extremely relevant in coping with chronic disease and the course of the disease. By social support is meant e.g. giving information, practical aid, emotional assistance provided by members of the informal care system or social network of the patient as well as by the formal care system of the patient. The general idea is that social support directly as well as indirectly has a positive effect on health outcomes. A theoretical frame-work has been developed for testing concurrent hypotheses.

The international comparison is needed and important for several reasons. As indicated before comparison on an international level is needed to answer the research questions. The research questions will be answered by the comparative description of the several formal care systems in Europe and by an analysis of the actual behavior of the formal and informal care system, the role of these care systems in managing chronic disease and their influence on the course of the chronic disease.

Especially attention will be given to the role of the informal care system (in interaction with the formal care system) in contributing to better outcome in the disease process and to the testing of several concurrent hypotheses which are now discussed in the literature in a longitudinal, cross-cultural design.

The international comparison is important to increase the statistical power of the study by the larger number of cases.

The international set-up of the study will result -additionally- in cross--culturally assessed tools for measuring social support (formal and informal) and coping with incapacitating diseases;

Also the scientific knowledge on the contribution of the several formal care systems to the course and outcome of the disease will increase by the international design. An additional 'result' of the study will be the cooperation between hospitals and universities on an interdisciplinary base within countries and, even more important, an interdisciplinary cooperation through Europe, which may contribute to the exchange of researchers and students in the future (besides the exchange within this study).

At the short run the output of the study will already be:

— well translated internationally usable instruments;
— the assessment of cross-culturally useful measures on specific key concepts, which are important in the international literature;
— presentation of results of a pilot study among a small group of patients in a few participating countries;
— a description of the formal care system in participating European countries in relation to the care for chronically ill patients;
— a description of the characteristics of the patient-groups in the participating countries.

II RELEVANCE OF THE PROJECT

As indicated in the introduction the project is relevant because of the growing number of chronically ill patients in Western Europe and the expected effects of the formal and informal care systems on the course and outcome of the disease. In addition, the study also fits in an international scientific interest and in the targets of the World Health Organization which are formulated in the Health for All (HFA) program.

The concept of social support is directly related to several HFA targets. It is related to: healthy life styles, the effects of health promotion, coping styles and diseases and to the use of services. In the report by a subcommittee of the ACHR 'Health Research Strategy for Health for All by the Year 2000' (Geneva 1986), the role of a social support network is emphasized, both for promoting health and for responding to disease. It is stated that there is a great need for further understanding of the relations between stress, illness, social support and the use of medical services.

'One example of exceptional interest is research into the relationships between human attachments, illness and mortality. It is providing evidence that people whose attachments are weak are more prone to illness and early death. Although the mechanisms of vulnerability are not yet clear, it appears that support systems can buffer stressful experiences. Such networks can influence the use of health services and the adherence to medical regimens. This is pertinent to behavioural changes, such as smoking cessation or sanitation practices. Social support systems facilitate the development of coping strategies that help people to contain distress within tolerable limits, maintain self-esteem, preserve interpersonal relationships, meet the requirements of new situations and prepare for the future' (Annex 2, p. 61). The significance of further research on social support, coping or problem solving behaviour and active participation in health decisions is also mentioned in the ERAP/RHFA document of the WHO European Office. Social support is explicitly related to target 14: "By 1990, all Member States should have specific programmes which enhance the major roles of family and other social groups in developinng supporting healthy life styles". Whereas the target limits itself to healthy life styles, this is also of significance to targets concerning primary health care and various others.

Because of large scale demographic changes, as well as changing patterns of disease, proportionally more people will be affected by chronic conditions. Such changes have massive effects on an individual level as well as on that if health care delivery systems and the public health policies in which they are based.

As European Governments become increasingly concerned with the costs and benefits of particular health policies, the analysis of the relationship between social support and chronic disease could have particularly important policy implications. If different degrees of social support are shown to have effects on the course and outcome of chronic conditions, then this may result in a significant shift of emphasis in health care policies, and especially towards the potentially cost effective endorsement of the informal sector. In any case the

formal investigation of the role of social support is likely to lead to a significant understanding of additional factors which influence the quality of life of those with chronic diseases.

Instruments have now been developed in several countries which ask for international exchange for standardization. Besides methodological questions there is a need for further theoretical specification because of competing hypotheses and the rather weak explanatory power of several models. International research will increase the relevance of the outcomes in this respect. Through international comparison the time — and place-bound effects can be accounted for. As indicated, social support systems have great potentials to improve the health situation and quality of life of the population, especially of risk groups. Further research action is necessary to develop these potentials. For practical reasons this proposal is limited to one chronic disease, i.e. chronic rheumatoid arthritis.

III RESEARCH AIMS AND RESEARCH QUESTIONS

As indicated in the introduction the objective of the EURIDISS-project is to understand the role of the informal and formal care system in managing chronic, incapacitating diseases and how both systems affect the course of the disease process. Therefore the functions of social support and social networks on the course of the chronic disease will be investigated. Special attention should be paid to the influence of medical treatment in this process and how other intervening variables influence the daily functioning and the quality of life of the persons involved: Also the interactions between formal and informal care for the chronically ill will be studied. The outcomes of these interactions could lead to suggestions for improving the care system.

The research questions are then:

1. what are the relations of social support and social support networks as given by formal and informal care system on the functioning and quality of life of chronically ill patients? Special attention will be paid to stress buffering effects of social support and to the role of physician's predictions and self-evaluations of the course od the disease.
2. what are the interactions between formal and informal care. What are the effects of these interactions between formal and informal care system on the evolution of the disease, on the functioning of the patient and on the quality of life?

IV THEORETICAL MODEL AND HYPOTHESES

These two research questions are elaborated in a theoretical model, which leads to general formulated hypotheses. A short outline of this theoretical model will be presented.

The theoretical starting point of the 'EURIDISS research project'is found in

the so called 'disease-handicap' model which has been slightly modified due to theoretical perspectives (Locker, 1983; Wiersma, 1986) (Figure 1)

Fig. 1 — Adjusted disease-handicap model

DISEASE ----------> IMPAIRMENT ----------> SOCIAL LIMITATIONS (handicap)

In this model disease stands for the etiology which causes changes in structure and functioning of the body (pathology); impairment is then defined as any absence or deviation of a psychological, physiological or anatomic structure of function; it is the exteriorization of the pathological situation and principally reflects the expression of the pathological situation and of the disease at the organ-level. Finally, social limitations have been defined as dysfunctioning in a social role or in some aspect of social behaviour. Additional to social limitations other 'outcome' variables referring to e.g. aspects of "quality of life" or survival will be assessed. Implied in this model is the contention that personal and social (coping) resources affect or intervene with the relationship between disease and the "outcome" of the disease. When this contention is implied more explicitly into this general theoretical model it can be elaborated into a general model as the basis for our research and the most important "variables" within it.

Based on figure 1 the most important variables to be included are:

- objective disease-characteristics (diagnosis; prognosis);
- changes in functional status and subjective (lay) characteristics/definitions of the chronic condition;
- outcome variables: social limitations (SL) i.e. activity restrictions (ADL/IADL) and role changes (RC), survival and quality of life (QoL).

The relationship between these variables will be influenced by "intervening" variables:

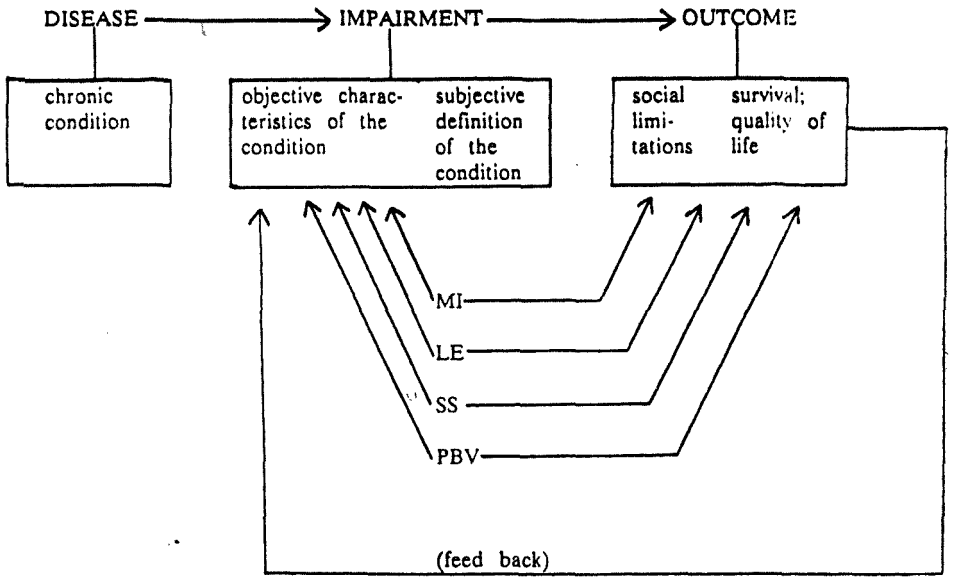
- medical intervention (M.I.);
- (other) life events (LE);
- aspects of social support (systems) (SS) (i.e. informal as well as formal care, assistance and treatment facilities);
- person-bound variables (PBV) (personality; socio-demographic variables; SES; etc.).

Directly or indirectly these intervening variables will affect the quality of life or survival of the afflicted persons and the improvement/deterioration of the condition (Figure 2).

Based on this general theoretical model several hypotheses could be formulated. The main hypotheses are generally formulated here and will be specified during the project. These hypotheses are:

1. Increasing level of impairment will lead to a worsening of outcomes depending on the level of SS and LE;

Fig. 2 — General theoretical model



Note. MI = Medical Intervention
LE = Life events
SS = Social support systems
PBV = Person-bound variables

2. Increasing level of impairment will lead to changes in social support (in a quantitative as well as in a qualitative way); both will influence outcome;
3. Impairment will affect the level of social support. Decreasing level of SS of persons with a chronic disease will decrease the ability to cope with LE. This decreasing ability will make LE more pronounced which will affect outcome;
4. Differences in level LE and/or SS will affect level of impairment.

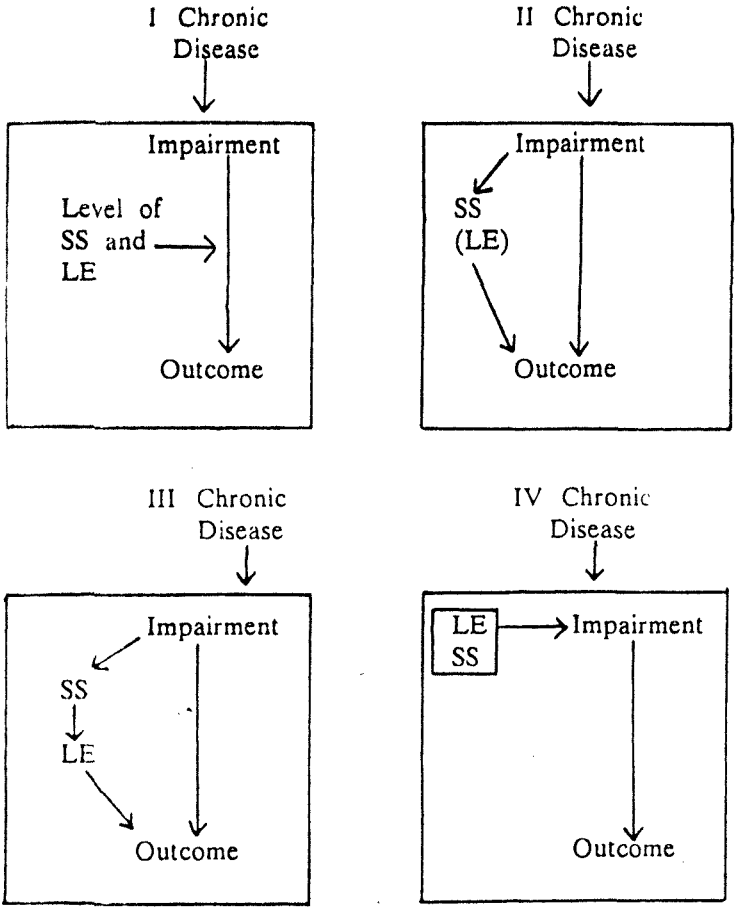
In figure 3 the bypotheses are presented schematically.

The hypotheses do not totally exclude each other, indicating the complex and interactive process on the one hand the necessity to study the actual relationships on the other hand. So it can be said that hypotheses 1 and 2 are concurrent ones, while hypothesis 3 is an elaboration of hypothesis 2. Although hypothesis 4 seems to be concurrent with hypotheses 1 and 2 it may be expected that both effects (H4 and H1 or H2) occur. Also one should be aware of the specific effects, SS, LE and other variables could have on specific outcome-variables.

V DESIGN OF THE STUDY

To answer the research questions and to study the hypotheses it is necessary

Fig. 3 — Elaboration of the general theoretical model into partial models corresponding to the main hypotheses.



Note. LE = Life events
SS = Social Support
Outcome = Social Limitations (SL)/Quality of Life (QoL)/survival

to use a longitudinal design with several measurement points in order to detect the effects and changes over time.

Apart from these basic research questions which can be answered by assessing the several key variables at least at three points of measurements, a number of other interesting relationships can be explored such as the effects of independent/intervening variables on specific outcome-variables and the interaction between outcome-variables. The role of the formal care system is an important mechanism in the study to understand the process from chronic disease to 'outcome'. The value of the international study is that this role of the formal care system can be analyzed in comparing countries with different care

systems. In the protocol a detailed list of the use of services over time will be administered. To be able to interpret the answers a description has to be made of the 'care system' of each participating country. Such a description is available from several countries (France, The Netherlands, Denmark, England, Germany) because of other international research projects. The methods (and results) of these studies will be used in this research project.

VI SELECTION OF CHRONIC DISEASES

Should results of an international research project as proposed here be comparable, then it will be necessary to develop further criteria for inclusion of any specific chronic disease. Therefore, we applied the following criteria for selection:

1. Frequency of disease (incidence/prevalence) assuring the availability of (enough) cases for constituting the sample;
2. Clear diagnosis, internationally admitted and done within reasonable time interval (symptoms-diagnosis);
3. Good objective scoring of the biomedical aspects of the disease;
4. Progressiveness of the impairment expected in reasonable time intervals (2-3 years).

There are good reasons to choose chronic rheumatic arthritis (RA) as chronic incapacitating condition to be studied by the research network participants. It is a common chronic disease which causes a lot of inconvenience for the patients and has a significant impact on the health care system. Recently rheumatic disease have become of interest in several countries.

Besides, the criteria of selection mentioned above do apply very well to rheumatoid arthritis. This is why the group has proposed that all network participants choose this chronic condition.

Additional chronic diseases should be chosen by at least two network participants. The following conditions are proposed:

— cancer, especially resected bronchogenic carcinoma;
— multiple sclerosis;
— ankylosing spondylitis.

To explore random effects at the beginning and at the end of the project, it is advisable to have at least two network participants choosing a healthy reference group. This reference is needed because of:

— the lack of information about degrees of support levels of individual functioning and cultural differences;
— controlling for life events not related to the disease;
— possible non linear relationship between independent and dependent variables;
— validating the model.

At this moment, the French team is planning such a control study.

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60 cáps.	1.944$00	1.555$00	389$00
Injectável 5 × 2ml	1.142$00	914$00	228$00
Duo — (20 + 5)	1.884$00	1.507$00	377$00

NOVO AIN

Calibral

Tenoxicam ®

Liberdade no Movimento 365 dias

TOMA ÚNICA DIÁRIA

SEM NECESSIDADE DE INTERRUPÇÃO NOS TRATAMENTOS A LONGO PRAZO

SEM NECESSIDADE DE AJUSTAR A DOSE EM DOENTES HEPÁTICOS, RENAIS E IDOSOS

SEM FENÓMENOS DE ACUMULAÇÃO OU SOBREDOSAGEM

	P.V.P.	EST.	UTN.
10 comp.	942$00	754$00	188$00
50 comp.	3.533$00	2.827$00	706$00
C.M.T.D.	70$66	56$54	14$12
10 sup.	902$00	722$00	180$00
C.M.T.D.	90$20	72$20	18$00

POSOLOGIA: 1 comprimido (20 mg) ou 1 supositório (20 mg) uma vez por dia sempre à mesma hora.

APRESENTAÇÃO: Embalagens de 10 e 50 comprimidos ranhurados.
Embalagens de 10 supositórios.

Esclarecimentos mais detalhados são fornecidos pelo Dep. de Informação Médica (Tel.: 893522)

Firma importadora: **QUIMIFAR, LDA.** – Av. E.U.A., 51, 4.º 1700 LISBOA

Firma preparadora: Kali-Chemie Pharma GmbH Hannover Alemanha

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CHAPTER TWO: RHEUMATOID ARTHRITIS — SAMPLING, MEASURES AND ANALYSIS

I POPULATION SAMPLING

I.1. Introduction

This chapter deals with the methodological, statistical and operationalization matters of the survey. The starting point is the definition of the population of the study, as far as rheumatoid arthritis (RA) is concerned, and the selection manner of the cases to be included. Measurement methods of the disease and its functional consequences during the follow-up (behavioural changes, quality of life) and of independent and intervening variables are then exposed. The planning of the analysis of the collected data is finally developed. The proposals, instrumensts and selection criteria made in an earlier stage, have been agreed on by the participating teams.

After the expert meeting/workshop in Brussels (15 and 16 March, 1986) on invitation of the EC/Comac HSR, and after the proposal was send to Brussels in spring an additional workshop has been organized, sponsored by the WHO — Euro. At this workshop the protocol and procedure were discussed in detail and the participants agreed on the project. Besides it was indicated that most participating teams will have national money available.

I.2 Definition of the disease

The criteria for diagnosis of RA have been established by the American Rheumatism Association (ARA). They are internationally validated and will enable inter-countries comparisons. The clinical diagnosis must be established by a rheumatologist. When four or more of the seven following criteria are present, the diagnosis of RA will be settled (ARA 1987 revised criteria):

1 — Morning stiffness for at least one hour and present for at least six weeks;
2 — Swelling of three or more joints for at least six weeks;
3 — Swelling of wrist, metacarpophalangeal or proximal interphalangeal joint for six or more weeks;
4 — Symmetric joints swelling;
5 — Hand roentgenogram changes typical of RA that must include erosions or unequivocal bony decalcification;
6 — Rheumatoid nodules;
7 — Serum rheumatoid factor by a method in less than 5% of normals.

I.3 Inclusion criteria

— Both sexes;

— 20 to 70 years-old at the onset of the survey;
— Delay between entry in the cohort and time-diagnosis of RA less or equal to 4 years;
— ARA criteria for diagnosis of RA are to be fulfilled at entry in the cohort;
— Patients should give an informed consent.

I.4 Exclusion criteria

— Existence of another physical handicap prior to the disease onset;
— Association with other severe chronic diseases;
— Malignant AR with systemic vasculitis;
— Very disabling RA (stage IV of the Steinbrocker classification);
— Absence of a reasonable guarantee of follow-up.

I.5 Sampling method

Each national team includes the required number of patients for constituting the cohort of the study. To prevent biased sampling, it is very important to collect cases through the entire health care system in a definite geographical area (e.g. hospitals, public/private physicians, patients' associations, etc.). A clear definition of the disease as given in par I.1 of this chapter is needed and the ability to meet the sampling requirements will be a criterion for being part of the project.

According to the above mentioned requirements the first procedure aims at identifying all the health care professionals having RA patients in charge. At the onset of the study, these professionals are then asked to provide the complete list of RA cases they have diagnosed in the past four years, including those who were formerly treated by them. These patients will be included (record and measurement) over the one year T1 period. During this period of inclusion, the health care professionals should also record all the fresh incidence cases for inclusion and inform the national research team.

So, at the end of the one year intake period, five years incidence cases are then included in the cohort (i.e. one year fresh cases and patients diagnosed with RA up till 4 years before the start of the study).

I.6 Number of cases

The number of cases to be included in the study depends on the main null hypotheses and the type of performed analysis in terms of:

— the levels of outcome occurring during the follow-up period;
— the distribution of social support levels among subjects with RA;
— the lowest differences of outcome between subgroups we want to be able to detect;
— the significance level (say 5%);
— the desired power (say 90%).

All these requirements are not known initially and cannot be accurately estimated before inclusion of a reasonable number of patients.

However, with the above accepted error risks, 700 patients are needed if we want to be sure to detect a difference of 10% between two subgroups whatever the level of outcome. Probable inequality of subgroups and loss due to follow-up lead us to increase these minimal requirements to 1000. According to this number, 150 cases a team at the end of the study seems to be a reasonable and feasible achievement. The prevalence of RA is estimated about 3% and incidence about .1 — .3/1000 according to various European countries.

Each country must be able to include at least 50 annual incident cases. Thus at least 250 patients will be recruited in order to be sure to have approximately 150 patients at the end of the study left. In other words, the case load of the study will be built up as folows:

50 RA patients: diagnosed 3 to 4 years before start of the study
50 RA patients: diagnosed 2 to 3 years before start of the study
50 RA patients: diagnosed 1 to 2 years before start of the study
50 RA patients: diagnosed in the previous 12 months
50 RA patients: diagnosed during the first year of the study

250 patients in total

II MEASURES

II.1 Introduction

For reasons of comparison it has been decided that all network participants must have a certain number of variables and instruments in common. However each network member is allowed to select additional variables and operationalizations/instruments. Therefore, within the interview and self-report schedules (which together may not take more time than 90 minutes), space must be reserved to allow the network participants to include several other instruments. Two types of measurement instruments are available for.

— measuring the disease and the impairment and its functional consequences:

* measuring of disease/impairment through clinical, biological and radiological data;
* measuring the dependent variables, which are functional consequences of the disease/impairment, by social limitations (activities of daily living; instrumental activities of daily living; role changes), quality of life and overall physical and psychological health status;

— measuring independent and intervening variables in order to assess their predictive value: self-evaluation, life events, social network, social support, medical intervention, use of health services, person-bound variables.

For all the instruments, standardized coding procedures and schemes are available and they have been presented and discussed at an Euridiss Workshop, held in Groningen, Holland, May 31 and June 1 - 2 (1989).

II.2 Disease and impairment variables

Clinical data:

— Pain (visual analogue scale);
— Morning stiffness (time);
— Grip strenght;
— Ritchie index (score-value);
— Subcutaneous nodules;
— Number and duration of acute phases since the last time of measurement;
— List of treatment (type, duration, doses).

Biological data:

— Haemoglobin, blood cells counts (including platelets);
— ESR, CRP, Fibrinogen;
— Rheumatoid factor by method giving less than 5% false positive assessed in a standardization laboratory (C II);
— Total serum protein, albumin and seroprotein electrophoresis.

At each measurement time, a 5 ml serum sample will be stored at -20°C in the standardization laboratory for further investigations.

Radiological data:

— Hand roentgenogram (front view of both hands on the same film, LARSEN's score;
— Feet roentgenogram (front view);
— Cervical spine (front and lateral view).

II.3 Functional consequences of disease/impairment; Quality of Life (QoL)

In this paragraph several instruments are described by which functional consequences of the disease/impairment is measured. Of these instruments the following are referring specifically to aspects of Quality of Life as indicated by the patient: (1) Social Limitations, (2) Overall Evaluation of Health and (3) Psychological and Somatic Health. Quality of Life as indicated by the medical specialist is assessed by means of two instruments: the Karnofsky Performance Status Scale and the physician's prediction of health outcome.

Social limitations (SL)

In order to assess SL one should distinguish Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) and Role Changes (RC).

ADL/IADL:

The ADL/IADL scoring, as a good approach for quantifying disability, will be used as the main judgement criterion.

A relevant tool is at our disposal: the Stanford Health Assessment Questionnaire (HAQ) in its modified version (Kirwan & Reeback 1986). The HAQ was especially elaborated and validated for the field of RA. This instrument will be completed in a clinical setting.

Besides this disease-specific instrument, a more general disease non-specific instrument measuring ADL and IADL will be used i.c. the Groningen Activity Restriction Scale (GARS). It allows a comparison between diseases. In a few studies this GARS has turned out to be a strong hierarchial polychotomous ADL-IADL scale (Kempen & Suurmeijer 1989).

Role Changes (RC):

For some primary areas of social functioning a few items have been formulated to measure role changes due to the disease/impairment: occupational/provider role, parental role, partner role (including sexual role), social participation role. The items are based on the studies of Michielsen et al. (1987) and Michielsen (1988), Hyman (1971), Suurmeijer et al. (1986) and Wiersma (1986).

National tems can, as an option, elaborate this instrument.

Overall evaluation of health (OEH):

The one item of the OEH as used e.g. by Blanchard et al. (1985), Briancon et al. (1986) and Goldstein et al. (1984), is used.

Besides measuring the health status of a patient at a certain point in time, this one item version also appers to have good predictive power for future health outcome.

Psychological and somatic health:

In order to assess psychological and somatic health two instruments have been chosen.

The General Health Questionnaire (GHQ):

The GHQ will be used to assess psychological health (or psychological well-being). This instrument also incorporates sub-scales on anxiety and depression. These dimensions seem to be relevant while a severe disease might be a threat to the patient and thus leading to anxiety reactions and it might give feelings of hopelessness and loss as well which implies that a depressive reaction is anticipated. The GHQ already has been used in a lot of research projects in several countries. Hence the instrument is already being used in several languages and validation of the instrument has been worked out extensively (Goldberg 1972; Sanderman 1988).

The Nottingham Health Profile (NHP):

The NHP will be used to assess perceived somatic health and is studied by a

European working group in order to validate the instrument in several countries (Hunt et al. 1981; Kind & Carr-Hill 1987).

Prediction of health outcome by the physician:

Two instruments measuring the health outcome as predicted by the physician are used. The one is the Karnofsky Performance Status Scale (KPSS). This index as applied mostly to cancer patients appears to have good predictive value for health outcome.

The other one is a two item version asking for the physician's prediction of health outcome (PPH) for a period of six and twelve months.

II.4 Independent and intervening variables

Self evaluation or the "subjective definition of the rheumatoid condition" (SDRC):

Subjective condition of the disease has well approved to be of influence on behavioural and health outcome (Suurmeijer 1980; Waltz & Badura 1988; Waltz et al. 1988) and is theoretically elaborated in the so called ABC-X model (Hill & Hansen 1964; Lavee et al. 1985; Young 1983), the "Behaviour Intention Model" (Olivier & Berger 1979) and in the cognitive appraisal processes of Cohen & Lazarus (1979).

The items formulated in the SDRC refer to "severity", "dependency", "shame" and "general adjustment".

Social Support Questionnaire of Transactions (SSQT):

Social support has well established its meaning in relation to health and other "outcome" such as the "use of services" (McKinlay 1971; Orth-Gomer & Unden 1987; Thoits 1982; Waltz & Badura 1988; Waltz et al. 1988; Ward et al. 1984). There are several ways and many instruments for measuring social support (Orth-Gomer & Unden 1987; Van Sonderen 1986). For this EURIDISS project items measuring actual transactions of social support have been chosen. Most of these items are based upon a longitudinal study on social support in the Netherlands. The items chosen are very highly loading on the emotional and instrumental dimensions (factors) of social support distinguished in this longitudinal study. The results of this study are still being analyzed.

The satisfaction with the social support is measured by the assessment of differences in the social support expected compared to that what was actually received.

Social Network Delineation Questionnaire (SNDQ):

To determine the actual and potential number of informal caretakers, information needs to be gathered on the core social network of the patient i.e. persons who provide the patient with actual instrumental and/or socio-emotional support (several items in the SSQT) as well as on the total social network of the patient for which the SNDQ has been developed. The SNDQ

provides information on the number of persons, sex, age, travelling distance and frequency of contacts for each subset of person or type of role relationship. This information is important in relation to the kind and amount of support received from informal caretakers, the "vulnerability" of the core social network as well as the use of professional facilities (Freidson 1973; Kempen & Suurmeijer 1988, 1989; McKinlay 1973, 1981; Oosterbaan & Zeldenrust 1985).

Health Services Interview (HSI):

The quantitative aspects of the utilization of health care facilities is measured by the number and types of healers/therapists/services contacted with during the last 12 months as well as by the number of contacts patients have had with these healers/therapists/services during the last 12 months, because of the illness.

Besides from the clinical data, information will be gathered concerning the medical intervention (type, duration, costs of the treatment).

Socio-emotional support given by formal or professional workers is measured by the general formulated items on social support from the SSQT. Also, satisfaction with this type of support will be assessed in terms of a discrepancy between expected and actual support transactions (see section on SSQT). Furthermore, items have been formulated to measure general satisfaction with professional aid. Because information about the diagnosis, treatment and prognosis of the disease is supposed to be important for (health) outcome e.g. compliance with therapies, social limitations, etc., (Mazzuca 1982; Suurmeijer 1985) items are formulated about the amount and the contents of the information given by the professional caretakers. These items are based on a study on cancer patients (Van den Borne & Pruyn 1985).

As an option, the use of health care facilities may be studied more intensively and/or extensively. This can be done, for example, by elaborating the answer categories of the ADL/IADL "b-items" of the GARS or by specifying the "open questions" in the HSI. Especially, the type and amount of care provided by voluntary organizations, self help groups/organizations, and informal central caregivers (see also II.6) should be studied more in depth. For both (GARS; HSI) more elaborated versions of the instruments proposed in Appendix A, are available.

Person-bound variables (PBV):

Demographic variables: Socioeconomic Status (SES), level of education and income. The effects of these variables on health outcome has been amply demonstrated (Blaxter 1981; McKinlay 1972, 1973; Townsend & Davidson 1982). Probably, they are also related to the variables mentioned before.

For measuring SES: see Treiman, 1977; level of education: see the International Standard Classification of the Unesco (ISCED), 1975 and the Standard Classification of Education-SOI of the Dutch Bureau of Statistics, 1978. Income level will be assessed in ECU's by amount of money/household.

Self-esteem (SE):

Self-esteem is of particular interest as one might suppose that a severe chronic disease is a threat to the self-esteem. A decrease in self-esteem might subsequently have a deleterious effect on health. It will be assessed with a short -internationally used- instrument: the Rosenberg self-esteem questionnaire (Rosenberg, 1961).

Life Events Interview (LEI):

Life-events (e.g. loss of work, severe illness of partner, divorce, death) are of significance in the onset and outcome of psychological and somatic disorders (Brown & Harris 1986; Sanderman 1988).

However, the role of stress is somewhat unclear because of a differential vulnerability effect, i.e. not all patients will deteriorate because of the exposure to stress.

In order to get more insight into the precise role of stress it is of great importance to study its effect in combination with other variables (such as social support).

The assessment of life-events will be carried out in a structured interview format in order to overcome the weaknesses of a self-report procedure. Specifically the EURIDISS-project gives the opportunity to highlight the possible role of both stress variables and intervening variables because of its longitudinal design.

II.5 Schedule

As illustrated we need a longitudinal design. The follow-up of the patients will be 3 years, with a view to building up the research population.

Each subject will be tested and selected according to the following schedule till the end of the period of measurement.

T-1 = first measurement (newly diagnosed cases and patients diagnosed with RA up till 4 years)
T-2 = 12 months after T-1
T-3 = 24 months after T-1

The newly diagnosed cases will be included over a one year period. Each subject will be followed up during three years with three measurement points.

II.6 Collection of data

Apart from the instruments, it is proposed to have a rather strict assessment procedure in order to get an optimal equivalence of material gathered in several research institutes/countries. In order to minimize differences on the assessment tools, the self-report questionnaires and interview schedules, should

flameril R

(diclofenac de sódio)

flameril EMULGEL

diclofenac dietilamónio

ARTROSES
ARTRITE REUMATÓIDE

FLAMERIL R

Apresentação: Diclofenac de sódio — Drageias de libertação prolongada a 100 mg.

Indicações: Formas inflamatórias e degenerativas de reumatismo.

Posologia: 1 drageia/dia.

Contra-indicações: Úlcera péptica, hipersensibilidade conhecida à substância activa, ácido acetilsalicílico ou a outros fármacos inibidores da prostaglandina sintetase.

Precauções: História de doença gastro-intestinal, insuficiência hepática, cardíaca ou renal grave. Gravidez. Doentes medicados com diuréticos e após intervenções de grande cirurgia.

Efeitos secundários: Os efeitos secundários gastro-intestinais são habitualmente ligeiros. Raròs: úlcera péptica, hemorragia gastro-intestinal, discrasias sanguíneas, alterações da função hepática e renal, bem como eritema multiforme e reacções de hipersensibilidade, tais como broncospasmo ou reacções sistémicas anafiláticas/anafilactóides.

30 drageias = 1 mês de tratamento.

PVP	SNS	— 1466.00
	UTENTE	— 366.00
Custo/dia	SNS	— 49.00
	UTENTE	— 12.00

FLAMERIL EMULGEL

Composição: 100 g de FLAMERIL EMULGEL como substância activa O-(2,6-dicloroanilino)-fenilacetato de dietilamónio+diclofenac dietilamónio), correspondendo a 1 g de diclofenac sódico.

Indicações: Para o tratamento local de situações inflamatórias dolorosas de diversas etiologias.

Posologia e aplicação: Conforme o tamanho do local doloroso a tratar, aplicar 2-4 g de FLAMERIL EMULGEL (quantidade do tamanho duma cereja a uma noz) 3-4 vezes por dia nas partes afectadas e friccionar levemente.
O FLAMERIL EMULGEL pode também empregar-se como tratamento adjuvante com outras formas de administração do FLAMERIL.

Contra-indicações: Hipersensibilidade ao diclofenac, ácido acetilsalecílico, e outros anti-inflamatórios não esteróides, assim como ao isopropanol ou ao propilenoglicol.

Precauções: O FLAMERIL EMULGEL só deve aplicar-se em superfícies de pele intacta, e não em feridas cutâneas ou lesões expostas. Deve evitar-se o contacto com os olhos ou com as mucosas. Nunca deve ser tomado pela boca.

Apresentação: Embalagem de 100 g.

PVP	SNS	— 845.00
	UTENTE	— 845.00

Informação completa do produto à disposição da classe médica.

Apartado 22
2726 Mem Martins Codex
Portugal
Telefone 921 22 21
Telefax 921 91 10
Telex 16030 Normal P
Telegramas Normal Mem Martins

Laboratório Normal

Produtos Farmacêuticos, Lda.

SEDE: Estrada de Casais - Alto do Forte - Mem Martins / Matricula n.º 1389 da Conservatória de Sintra / Capital Social: Esc. 250.000.000$00

originate from the same English version. Also, the format of the questionnaire and the interview procedures should be equal for all countries. The interviewer should not be a member of the treatment staff; it should be clear to the patient that the assessment is not linked to treatment procedures and that no information will be given to any member of the medical team. The interviewer will have a specific training following a written instruction. Also the introduction of the research in hospitals or other places and the conditions of cooperation should be specified by each team and controlled for' (see chapter 3 on "International coordination").

As indicated before, besides the patient it is worthwhile to interview a person in the informal care system about the situation of the patient. (see also II.4) The relevance of interviewing a "significant other" from the informal care system of the patient has amply been discussed during a Euridiss Workshop, held in Groningen, Holland, May 31 and June 1 - 2 (1989). However this again has to be decided by each team and it is not a part of the international protocol. The patient is not allowed to be interviewed in the treatment department. Apart from the interviewer, no other person should be present during the interview.

More detailed data gathering procedures are already available and have been presented and discussed at the Euridiss Workshop, mentioned before.

III ANALYSIS

III.1 Descriptive aspects.

The distribution of clinical, radiological and biological data will be described according to demographic variables (sex, age, education, socioeconomic status, residence). Thus, evolutive staging of the disease will be established.

The instruments used to measure outcome are elaborated in order to construct scores or to obtain a rated scale. Distribution of these different scores will be described according to demographic variables and evolutive staging of the disease. The distribution of indices of social networks will be described according to demographic characteristics. Scores of global and specific (emotional instrumental) support will be calculated using an 'a priori' weighing of the measured variables and factor analysis in order to select the relevant information.

Inter-countries comparisons will then be performed, using all the information considered pertinent at the previous stage of the analysis. The statistical analysis will be developed according to the type of variables (analysis of variance, frequency tables etc.) Anyway, the comparison will be global, in a first step, to test the equality of means or frequency in all countries. According to the results, pairwise comparisons could be done, in a second step, to compare each pair of countries.

III.2 Hypotheses exploration.

Hypothesis 1 will be explored through linear regression between outcome (Tx) and levels of social support and LE (Tx-1), analysis of variance after qualitative transformation of the score of social support, and survial models for failure time data (i.e. data that have as a principal end point the time until an event occurs). Hypothesis 2 will be explored through the same process. The only difference is the choice of time measurement of outcome (Tx) and of social variables (Tx+1). Hypothesis 3 will be explored througt the same relation between LE (Tx+1) and outcome (Tx?2) after adjustment on level of social support (Tx) and impairment (Tx-1).

Hypothesis 4. Level of impairment (Tx+1) will be explained by level of SS and/or LE (Tx).

This has been elaborated in figure 4a and 4b.

Fig. 4a — Hypothetical relationships between basic variables in the study (Hypotheses I,II,III).

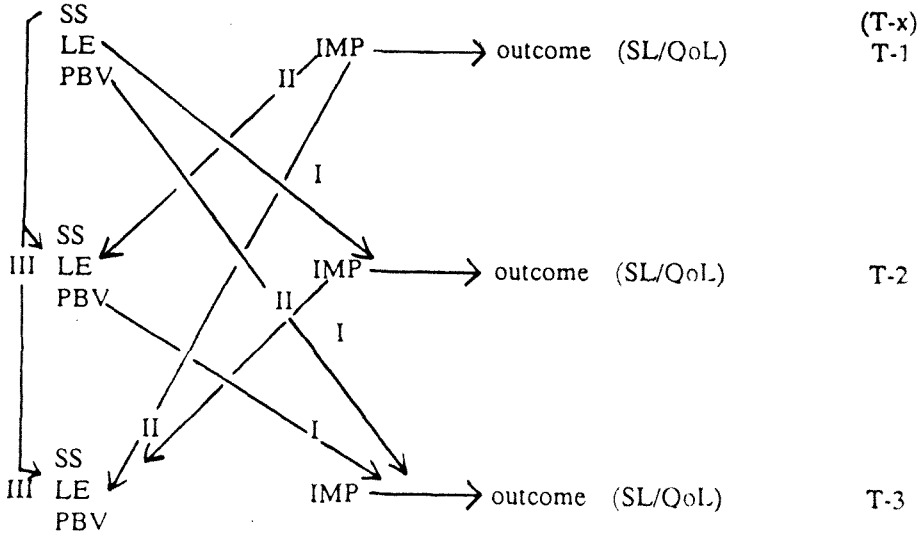
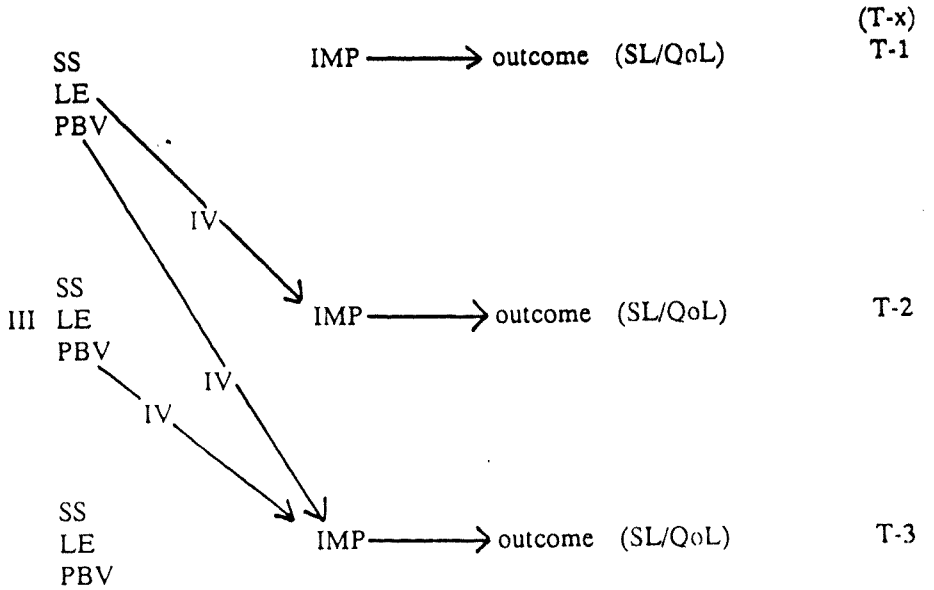


Figure 4a shows the interest to study the possible intervening/modifying role of social support and life events on the relation between impairment and outcome (I) and the "conditioning" effect of impairment on social support and through that on life events (II,III).

Descriptive aspects will be analyzed at the end of the intake period.

Hypothesis exploration will be performed at the end of each time period measurement taking into account all the previously recorded information. In such a way we will be able to produce results after each one year period.

Fig. 4b — Hypothetical relationships between basic variables in the study (Hypothesis IV).



Note. SS = social support; LE = life events; PBV = person bound variables; IMP = impairment; SL = Social Limitations; QoL = quality of life.

CHAPTER THREE: INTERNATIONAL COORDINATION

I ORGANIZATION STRUCTURE

I.1 International Project Leader (IPL) and Project Managing Group (PMG)

In Brussels, March 15-16, 1989, Prof. Dr. W.J.A. van den Heuvel has been proposed as the IPL of EURIDISS. Also, a PMG has been proposed. The members of the PMG are:

— The Netherlands:	Prof. Dr. W.J.A. van Heuvel (Groningen)
— France:	Dr. S. Briançon (Nancy)
— England:	Dr. I. Robinson (London)
— Norway:	Dr. T. Moum (Oslo)
— Belgium:	Prof. Dr. J. Dequeker (Leuven)

This list is provisional. Other members of the participating national teams may be added, especially from Portugal and Italy.

I.2 Special Task Force

Furthermore, a special Task Force will be needed consisting of the initiators

or the study, for watching data collection procedures and theoretical exploration.

— The Netherlands: Prof. Dr. W.J.A. van den Heuvel, Dr. Th. P.B.M. Suurmeyer, Dr. R. Sanderman (Groningen)
— France: Prof. Dr. M. Manciaux, Dr. S. Briançon (Nancy); Prof. Dr. F. Blanchard (Reims).

I.3 Participating members

The participating members/countries are:

— Belgium, Leuven:	Prof. Dr. J. Dequeker
— Denmark, Arhus:	Dr. T.I. Hansen
— England, London:	Dr. I. Robinson
— France, Nancy:	Prof. Dr. M. Manciaux
	Dr. S. Briançon
	Dr. Fr. Guillemin
Reims:	Prof. Dr. F. Blanchard
— Federal Republic of Germany, Oldenburg:	Dr. M. Waltz
(possibly): Ulm and Hannover	
— Greece, Iona:	Prof. Dr. H.M. Moutsopoulos
— Italy, Bari:	Prof. Dr. R. Numo
(possibly): Sienna	
— The Netherlands, Groningen:	Prof. Dr. W.J.A. van den Heuvel
	Dr. Th. P.B.M. Suurmeyer
	Dr. R. Sanderman
	Prof. Dr. M. van Rijswijk
— Northern Ireland, Belfast:	Dr. A. Bell
— Norway, Oslo:	Prof. Dr. E. Munthe
	Dr. K. Kvien
	Dr. T. Moum
— Portugal, Lisbon:	Prof. Dr. V. Queiroz
— Spain, Madrid (possibly)	
— Sweden, Goteborg:	Prof. Dr. A. Bjelle
— Switserland, Zurich:	Prof. Dr. F.J. Wagenhauser
— Yougoslavia, Zagreb:	Prof. Dr. S. Letica
(possibly): Belgrade	

II WORKING PLAN

II.1 Time table

Based on the study design and heard the experts and provisional participants at the workshop in Brussels (15-16 march, 1989) the following time table is proposed:

preparing/t1/t2/t3/final analysis
sept.1989/1990/1991/1992/1993 (November 30)

Based on the time schedule presented before the following activities are planned per period:

A. preparing period (sept 1989-dec 1989)

1. translations of the research protocol and instruments in the several languages. 2. feasibility studies in several countries. 3. checking the manpower, interdisciplinary composition and funds of the provisional participants.

B. t1 (begin till end 1990)

1. reporting on the activities in 1989, resulting in the start of the first measurement in march 1990. 2. data collection t1. 3. control on procedures in data collection. 4. control on the quality of the data. 5. checking the storage and correction of the data. 6. report on the functioning of the formal care system in relation to the care for chronic patients in the participating countries. 7. report on the global outcomes of the first measurement by each team (6 months data collection) 8. report on the usefulness and quality of the instruments.

C. t2 (begin till end 1991)

1. global comparison of the international data (based on B7).

2. deciding on the continuous use of all instruments (based on B7, B8 and C1). 3. checking the quality of data presented by each team. 4. data collection t2. 5. control data collection (see B3-B5). 6. full report on t1 data and comparison of 'fresh-old' patients.

D. t3 (begin till end 1992)

1. data collection t3. 2. control data collection (see B3-B5). 3. report on the first longitudinal data by each team. 4. first report on the international longitudinal data in international comparison.
5. exploration of the concurrent hypotheses (t1-t2).

E. t4 (begin till November 1993)

1. finishing data collection and definitive storage of all data. 2. report on the longitudinal data and main hypotheses by national teams. 3. report on the methodological aspects of the study (quality data, participation, instruments, etc). 4. more specific analysis on the longitudinal data, national and international (t1-t2-t3). 5. definitive testing of the theoretical frame work dealing with the interaction between formal and informal care. 6. report on the specific role the several formal care systems on the outcomes of the disease.

II.2 Plans for dissemination and publications.

The study will be reported in internal research reports, followed by articles in international journals. Besides, it is intended to publish several books about the main topics of the study (Topics could be: methodology and instruments, role of social support on the course of the disease, longitudinal changes among countries, the interaction between formal and informal care, the role of the

intermediating variables). Also, workshops will be organized, which may include some experts not participating in the research.

Of course, each national team will report the national results in their own country and (inter) national journals.

III COORDINATION

Each national team has to work on the common disease: rheumatoid arthritis. It is compelled to use the protocol prepared by the initiators of the project (the so called Groningen - Nancy - Reims group) as well as the same methods, instruments, criteria and to conform to the time schedule.

Such an ambitious inter-countries project does require efficient coordination mechanisms if it is to provide usable results and to allow for international comparisons. This coordination has to be organized in several ways.

— Project Managing Group (PMG) and International Projectleader (IPL):

The International Project Leader (IPL) and the Project Management Group (PMG) are responsible for controlling the working plan regularly, for evaluating the progress of the project, for developing and — in the case proposals are coming from teams — approving plans for the international comparative analysis and publications.

The PMG will work out a more detailed protocol dealing with the rights and duties of each participating team (i.e. regulations concerning the use of the protocol and on data collection, availability of the collected data, quality control of the data, exchange of data, publications etc.). During the workshop in Brussels the provisional participants agreed on the general arrangements on data collection, data control, pooling and responsibilities for international comparison as indicated in the plan.

— Special Task Force:

This Task Force, consisting of the members of the initiating teams of Groningen, Nancy and Reims, will control the quality of the international data collection and organize meetings and carry out quality control visits (see further on).

— Meetings/exchanges:

Regular meetings should be organized, aiming at:

- exchanging scientific information on the development of the project, reviewing new knowledge, discussing the scientific aspects of the work of each national team;
- strengthening the working links between teams, planning for new research avenues, joint publications. As far as publications are concerned, each national team is free to analyze and publish its own data. Consultation will be needed with the PMG as to the analysis and publication. Also, these data should be available for the international reports and publications in a form decided by the PMG.

Participants of the meetings will be the scientific leaders of national projects, or people more especially responsible for the specific aspects.

Besides, the other researchers involved in the project, could be important participants. In addition, external experts could be invited as well as representatives of other teams working on the same topic, with the same methodology, but not belonging to the group.

The PMG will meet twice a year to control and check the points indicated in the working plan and to propose workshops and reports. For the controlling of the data collection and storage of the data (B3-B5 etc) the special Task Force is responsible. The special Task Force will visit each national team once a year. In the beginning of the study a more intensive exchange of researchers will be organized (partly on bilateral basis) for standardization of procedures. At the end of the study this will be the case for the final analyses.

To coordinate the national reports the IPL will bring together (sub)groups of countries once a year. Additional to that, workshops will be organized for the international comparison (once a year) and for specific reports (see work plan). In order to carry out the international comparison the French team will be in charge of the international data storage. This team will provide each research team with a special. software program (IBM compatible). The file structure will be provided and at the beginning of the study technical details on data collection and recording of the data will be given to each national team. The French team will receive the collected data from each research team and be in charge of the central storage of the data.

As indicated before the international analyses (all countries or a specific group of countries) will be coordinated by the IPL and be approved by the PMG.

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CONFERENCE REPORT CONSENSUS DEVELOPMENT CONFERENCE: PROPHYLAXIS AND TREATMENT OF OSTEOPOROSIS

A consensus development conference sponsored by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the European Foundation for Osteoporosis and Bone Disease and the American National Osteoporosis Foundation, was help in Copenhagen from 19 to 20 October 1990. A panel of 14 listened to evidence from experts in public session attended by 2000 people, including representatives of the medical profession, the pharmaceutical industry, the press, and ministries of health. After a closed session, the panel discussed its report with the audience and a consensus statement was then presented at a press conference.

DEFINITION

Osteoporosis is a disease characterized by low bone mass, microarchitectural deterioration of bone tissue, and a consequent increase in fracture risk.

SIGNIFICANCE

Osteoporosis is a major cause of mortality, morbidity and medical expense worldwide. It afflicts an estimated 75 million people in the United States, Europe and Japan combined, including one in three postmenopausal women and a majority of the elderly. Osteoporosis causes over 1,300,000 fractures annually in the United States alone. Osteoporosis will be an even greater problem in the future, because the world population is aging and the incidence of osteoporotic fractures is increasing in many geographical areas. Hip fracture is responsible for much of the mortality and morbidity of osteoporosis, and is a leading cause of disability in the aged. 12-20% of hip fracture victims will die within 1 year of the event, and mortality rises progressively with advancing age. Moreover, the majority of hip fracture survivors are unable to perform the

activities of daily living unaided. A small but significant percentage will require permanent custodial and nursing care.

The high frequency of falls with advancing age contributes significantly to the likelihood of hip and other fractures in the elderly. Spine fractures are common causes of pain, deformity, loss of height and disability. The financial cost of osteoporosis in the United States each year exceeds 10 billion dollars.

RISK FACTORS AND CAUSES

Bone mass in the elderly reflects the accumulation and maintenance of bone tissue during growth and maturation, and the rate and duration of bone loss thereafter. Predisposing to osteoporosis are factors that induce a low peak bone mass, and those that underlie excessive postmenopausal and aging associated bone loss. Although our knowledge is incomplete, genetic, endocrine and life style factors are contributory.

At greatest risk for osteoporosis are White and Asian women who are thin or petite and have a family history of the disease. Estrogen deficiency is the main cause of rapid postmenopausal bone loss and contributes to aging — associated losses as well. Consequently, an early menopause may hasten the appearance of future osteoporosis. Premenopausal estrogen deficiency states also promote bone loss. Prolonged periods of inadequate calcium nutrition increase risk, and cigarette smoking, alcohol abuse, and a sedentary lifestyle are suspected risk factors.

Diseases or conditions known to cause osteoporosis (secondary osteoporosis) include hyperthyroidism, primary hyperparathyroidism, immobilization, multiple myeloma, and exposure to glucocorticoids in excess. Although white males and blacks of both sexes are at lowest risk, osteoporosis appears in all populations, and 1 in 5 hip fractures occur in men.

PREVENTION AND TREATMENT

Inhibitors of bone resorption

Estrogens

Osteoporosis is preventable. Estrogen therapy is the drug of choice for preventing bone loss in women after the menopause or in women with impaired ovarian function. Estrogen, by inhibiting bone resorption, reduces bone loss at all skeletal sites. The effects of estrogen persist for as long as therapy continues. The minimum fully effective oral doses are 0.625 mg conjugated equine estrogen or piperazine estrone sulphate per day; 2 mg 17β-estradiol per day; and 50-100 μg transdermal estradiol per day.

Epidemiologic data suggest that estrogen therapy given for at least 5 years early in the climacteric period reduces subsequent hip and Colles' fractures by about 50% and vertebral fractures by up to 90%.

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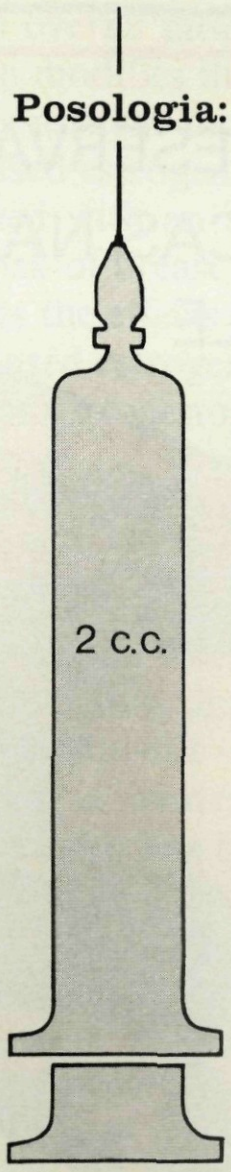

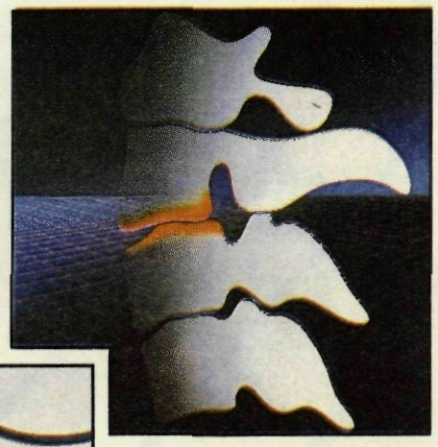

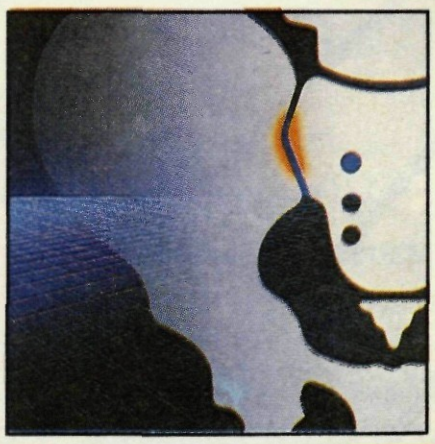

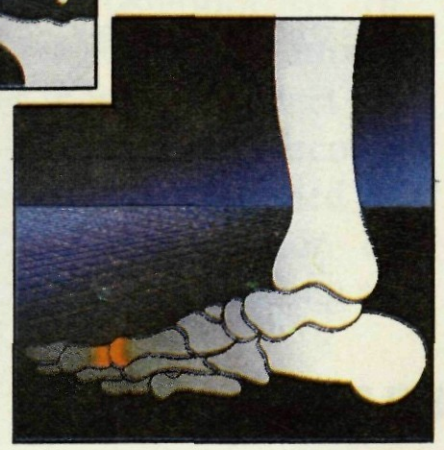

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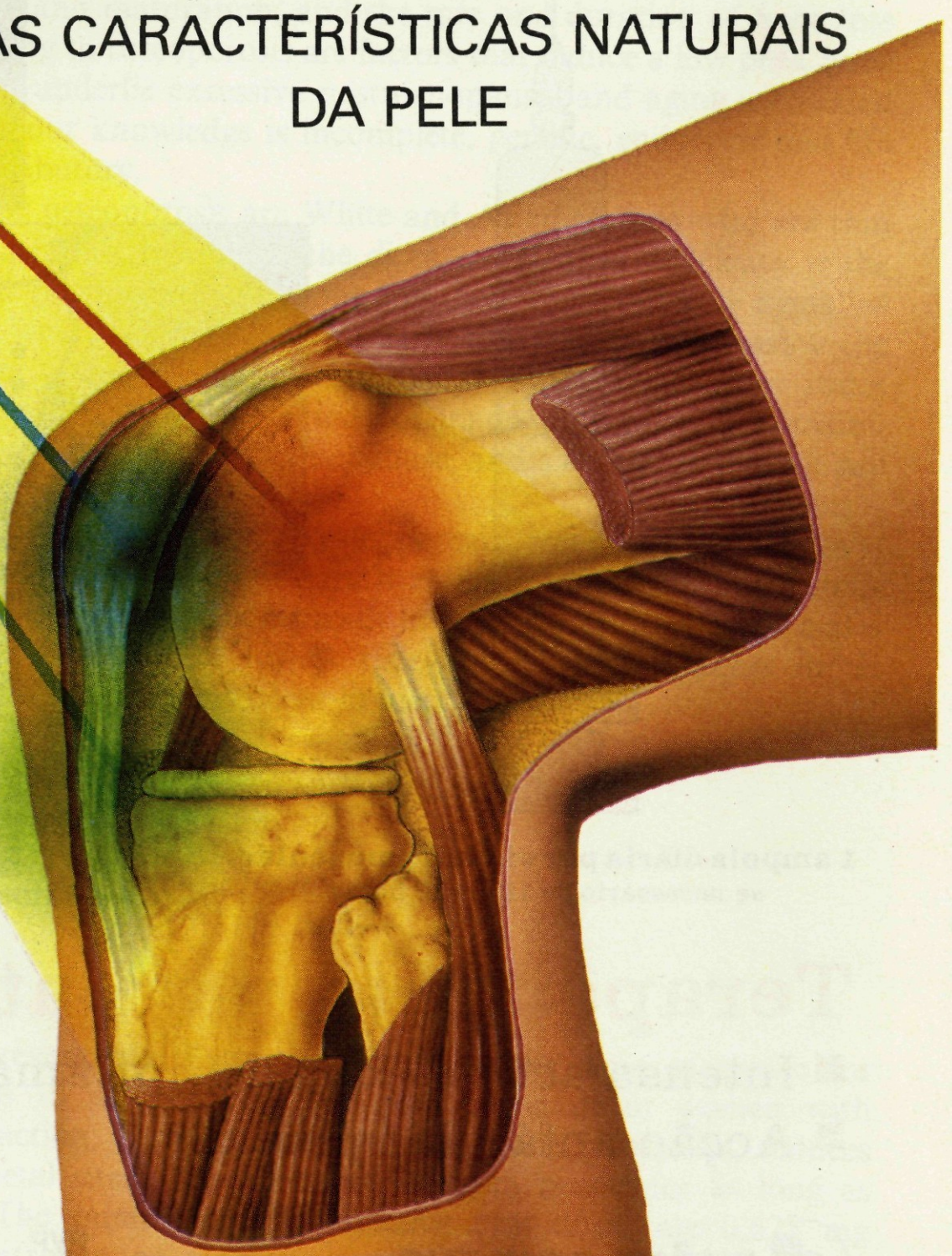

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The addition of a progestogen does not appear to impair the response of the skeleton to estrogen; some progestational agents may enhance the effect of estrogen. Estrogens may also be used in the treatment of established osteoporosis. The positive effects of estrogen have been demonstrated in patients up to the age of 70 years.

Critical review of published observational studies suggests that estrogen therapy decreases the risk of cardiovascular disease by about 50%, with a similar effect on overall mortality. It is not known whether combined therapy with progestogen modifies this benefit.

There is no consistent increase in the risk of breast cancer among women who have ever used estrogen therapy. Long-term therapy (more than 10 years) may be associated with an increase in the *diagnosis* of breast cancer, but no increase in the risk of breast cancer *death* has been shown. There is inadequate evidence to assess the effects of combined therapy on the risk of breast cancer.

Use of unopposed estrogen therapy increases the risk of endometrial cancer; adequate doses of a progestogen negate this increase.

Calcitonin

Calcitonin decreases further bone loss at vertebral and femoral sites in established osteoporosis, but effects on fracture frequency have not been demonstrated. Therapeutic regimens include injections or nasal spray. The effect of calcitonin is greater in patients with high turnover osteoporosis. In some studies calcitonin has been shown to prevent trabecular bone loss during the first years of menopause. It is not established whether there is an effect on cortical bone. Calcitonin appears to inhibit further bone loss in glucocorticoid-induced osteoporosis. The efficacy of calcitonin has not been determined in osteoporosis in men. Calcitonin provides an alternative in prevention of menopause-related bone loss in those women who are unable or unwilling to take estrogen.

Bisphosphonates

Several well-controlled studies indicate that orally administered bisphosphonates reduce bone loss and the incidence of vertebral deformity in patients with established postmenopausal osteoporosis. Data suggest that bisphosphonates reduce bone loss during the first year of the menopause and in patients with glucocorticoid mediated osteoporosis.

Calcium

The importance of an adequate calcium intake at all stages of life is well established. It is a prerequisite for normal bone growth, and for the attainment of peak bone mass. However, a high calcium intake will not substitute for

estrogen therapy in blunting the accelerated bone loss during the climacteric. Maintenance of an adequate calcium intake is also necessary in elderly subjects. A minimum intake of 800 mg of calcium daily is recommended for all adults. Higher amounts are required in childhood, adolescence, pregnancy, lactation and old age.

Stimulators of bone formation

The ideal therapy for established osteoporosis should stimulate bone formation and increase bone mass sufficiently to decrease the occurrence of new fractures.

Fluoride

Fluoride stimulates osteoblasts and increases cancellous bone mass. However, its effect on fracture incidence is controversial, and might be dose dependent. In a recent double blind, placebo controlled study of 75 mg NaF per day, hip fracture incidence was actually increased despite the rise in trabecular bone mass of the spine, and no change in vertebral fracture incidence. Earlier, less well controlled studies at lower fluoride dosage (up to 50 mg NaF) showed a beneficial effect on fracture rate. This might imply a narrow therapeutic window for fluoride and deserves further scrutiny. The known side effects of fluoride — gastrointestinal and arthralgias — have been decreased by changing the formulation, using other fluoride salts, and reducing the dose, but still remain a problem.

Anabolic steroids

Currently available anabolic steroids can increase bone mass in osteoporosis, perhaps by increasing bone formation. Their use is limited by side effects, which include virilization as well as adverse effects on carbohydrate and lipid metabolism and on liver function.

Parathyroid hormone

Promising data, in which parathyroid hormone increases total bone mass, justify the continued clinical investigation of this hormone as an anabolic treatment.

Other modalities

The positive effect of *1,25-dihydroxyvitamin D_3 and 1α hydroxyvitamin D*

on fracture incidence disclosed in some studies in osteoporotic subjects may reflect promotion of calcium absorption, especially in the elderly and those on low calcium intakes.

In conjunction with calcium intake, *weight bearing exercise* contributes to the development and maintenance of bone mass. In contrast excessive exercise sufficient to cause amenorrhea, is associated with bone loss due to accompanying ovarian insufficiency. There is yet no evidence that moderate physical exercise retards bone loss associated with menopause or aging. However, active exercise is considered useful in the elderly, particularly to improve muscular function and agility, and to reduce the likelihood of falls.

Other approaches to fracture prevention

Falling is the precipitating event in the majority of osteoporosis-related fractures in the elderly. Reductions in balance, muscle strength, and agility caused by aging, medications, and diseases are contributory. Hence, every effort must be made to reduce environmental hazards and modify therapeutic regimens that may predispose to falling. Vitamina D deficiency, which is commonplace in housebound elderly and may magnify the risk of hip fracture, should be prevented and treated.

SELECTION FOR EARLY AND LATE INTERVENTION

Bone mass measurement: Methodology

There are four basic techniques currently used for non-invasive assessment of the skeleton: single photon absorptiometry, dual photon absorptiometry, dual energy x-ray absorptiometry, and quantitative computed tomography. Other techniques, such as neutron activation analysis, compton scattering, ultrasonic transmission and magnetic resonance, either are not widely applicable or are incompletely developed.

Single photon absorptiometry (SPA) incorporates an isotope source, ^{125}Iodine, and a scintillation detector, and can be used to assess bone mass in the peripheral skeleton at sites where cortical bone predominates, such as the mid-shaft of the radius. Technical advances in SPA have improved both the precision and sensitivity of the method, and have provided the capability to assess trabecular bone enriched sites, such as the distal end of the radius or the calcaneus.

Dual photon absorptiometry (DPA) incorporates a dual-energy isotope, ^{153}Gadolinium, which permits scanning of thicker body parts. While spine and hip assessmment procedures are most widely used, DPA may be employed for the quantification of total body bone mass or any designated segment thereof. It is a somewhat time-consuming procedure.

Dual energy x-ray absorptiometry (DXA) utilizes an x-ray source in place of an isotope source, and provides improvements in detector configuration and

automation of analysis procedures. These have greatly increased both the speed and the precision of bone mass measurements. Overall performance has thereby been enhanced. Moreover, newer applications, such as lateral spine scanning in DXA, have been developed.

Quantitative computed tomography (QCT) allows the direct measurement of trabecular or total bone density, principally in the spine. Recent advances in software and hardware have substantially improved QCT performance by controlling technical parameters and automating the procedure. Decreases in scanning time, reduction in radiation dose, which still remains high, and semi-automated analyses have enhanced the clinical utility of this technique.

Bone mass measurements in diagnosis and assessment of therapy

Three general clinical needs can be addressed with bone mass measurements: (1) **Screening** of asymptomatic individuals, particularly perimenopausal women, to determine whether or not intervention is indicated on the basis on increased fracture risk; (2) **Diagnosis** of osteoporosis in patients with symptoms, or with other clinical indications, such as suspected low bone mass on radiographs; (3) **Monitoring** of treatment efficacy.

Each of these clinical applications places different requirements upon the technique employed for bone mass measurement.

For purposes of **screening**, the technique must be simple, safe, inexpensive, and it should relate adequately to the patient's overall fracture risk (irrespective of fracture site). *Bone mass measurements are required for accurate assessment of fracture risk in the individual patient.* It is now established that a single accurate measurement of bone mass at any site has equal predictive value for subsequent fractures of all types. The **diagnosis** of osteoporosis affecting a particular site of the skeleton requires bone mass assessment at the appropriate site.

For example, if vertebral deformities are detected on radiographs, measurement of spinal bone mass can determine whether significant spinal osteoporosis is present. **Monitoring** of treatment efficacy requires measurement techniques with high precision. In addition, the measurement site, and its cortical/trabecular composition, must adequately reflect the effects of particular therapeutic agents.

In addition to levels of bone mass, clinical decision-making also requires consideration of other factors such as current age, life expectancy, and anticipated (or measured) rate of bone loss (see below). Models have now been proposed which incorporate these variables, and provide estimates of remaining lifetime fracture probability. Such models can assist in determining which patients will benefit most from specific interventions.

Biochemical assessment of bone remodeling and osteoporosis

In the diagnosis of primary osteoporosis, it is necessary to exclude osteoma-

lacia and to assess secondary causes of osteoporosis. Biochemical markers of bone turnover are a routine part of the diagnostic examinations of patients with a number of metabolic bone diseases. They are also useful in the follow-up of such patients, e.g. to monitor the effects of intervention.

Markers of **bone formation** include serum total or bone specific alkaline phosphatase activity, serum osteocalcin (bone gla-protein) and the serum level of type I collagen propeptides.

Osteocalcin, the only protein that is specific for bone, is a sensitive and specific marker of osteoblastic activity. Radioimmunoassays of the carboxy — and amino-terminal propeptides of type I collagen have been developed; their sensitivity and specificity require further investigation.

Markers of **bone resorption** most commonly used are urinary calcium and hydroxyproline. Recently, efforts have been made to develop even more sensitive markers of bone resorption. Pyridinoline and deoxy-pyridinoline, derived from two crosslinks of collagen which appear to be specific for bone and cartilage collagen, have become available recently. Their levels are elevated in diseases characterized by a high bone turnover, are increased after the menopause, correlate with bone resorption measured on iliac crest biopsy specimens, and are not influenced by diet. Plasma tartrateresistant acid phosphatase reflects osteoclast activity but improved assays are needed.

There is growing evidence that the rate of postmenopausal bone loss can be determined by biochemical markers. One examination shortly after the menopause may help to predict the degree of bone loss in conjunction with a measurement of bone mass.

RESEARCH IS URGENTLY NEEDED TO DEVELOP

- Enhanced understanding of the epidemiology of osteoporosis.
- Improved understanding of the regulation of bone remodeling and mass, including mechanical, endocrine and local factors.
- New approaches to reduce postmenopausal and aging-associated bone loss.
- Delineating the factors that determine the accumulation of bone tissue during growth and maturation.
- Effective, safe low cost methods to restore healthy bone in osteoporotic patients.
- Accurate, easily accessible, low cost methods to predict the likelihood of osteoporosis and to monitor the response to therapy.
- Expanded knowledge of falling among the elderly (risk factors, causes), in order to design effective prevention approaches.

To be published in the American Journal of Medicine.

The panel comprised: R Bouillon, Belgium; P Burckhardt, Switzerland; C Christiansen, Denmark; HA Fleisch, Switzerland; T Fujita, Japan; C Gennari, Italy; TJ Martin, Australia; G Mazzuoli, Italy; LJ Melton, USA; JD Ringe,

Germany; P Riis, Denmark; WA Peck, USA; G Samsioe, Sweden; LE Shulman, USA.

Invited experts presenting evidence were: CH Chesnut, USA; SR Cummings, USA; PD Delmas, France; JA Eisman, Australia; HK Genant, USA; RP Heaney; USA; CC Johnston USA; JA Kanis, UK; R Lindsay, USA; PJ Meunier, France; AM Parfitt, USA; J-Y Reginster, Belgium; BL Riggs, USA; BJ Riis, Denmark; RD Wasnich, USA.

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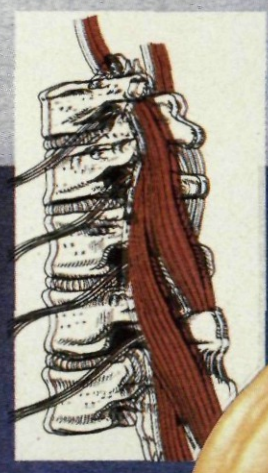

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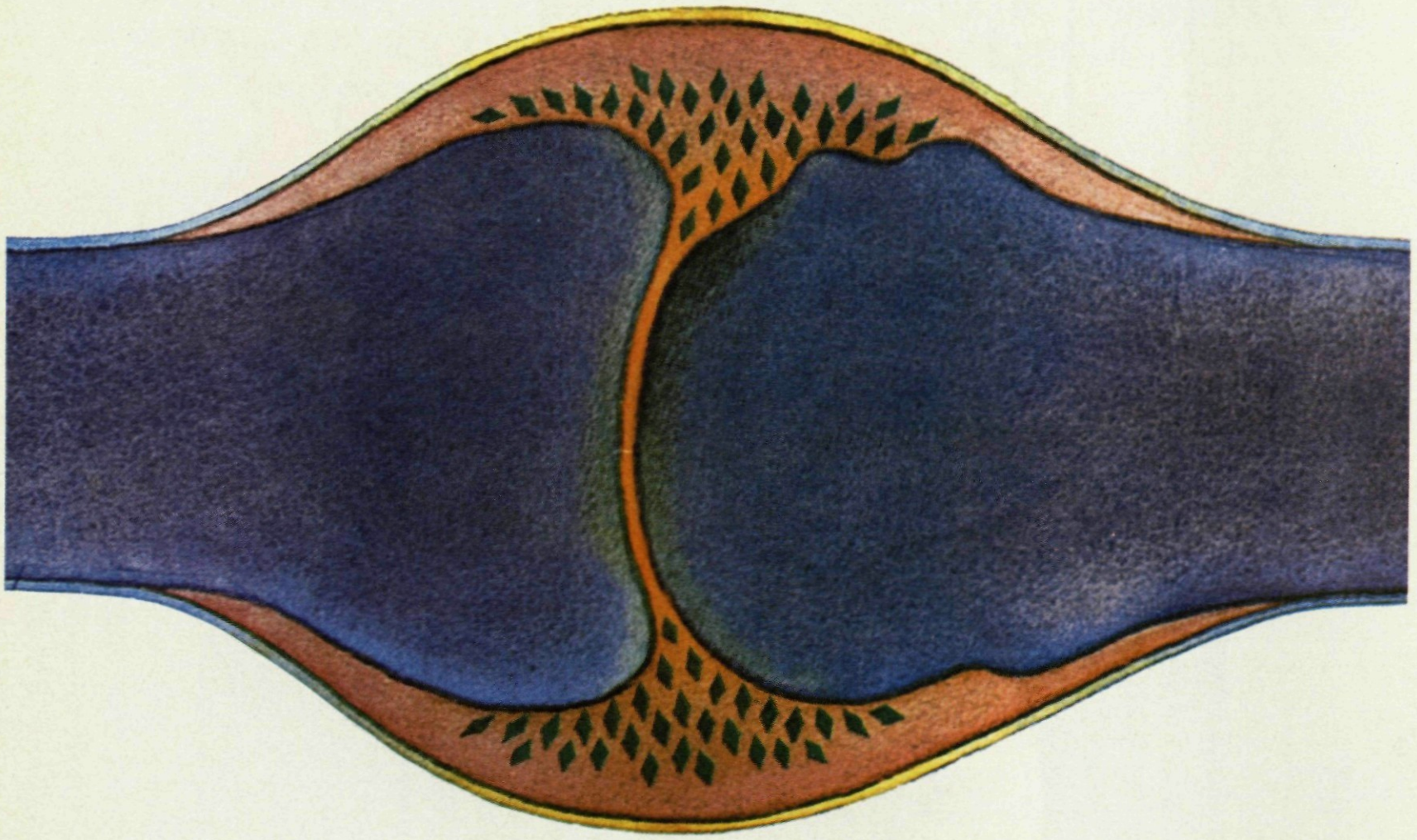

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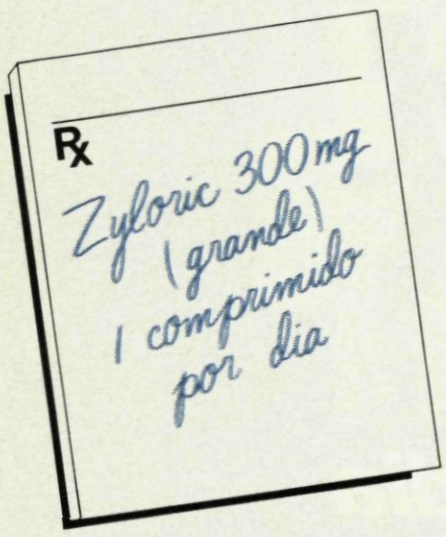

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ACTA REUMA. PORT., XVI (3): 159-166, 1991

COMBINAÇÃO DE ESPONDILITE ANQUILOSANTE E ICTIOSE LAMELAR NUM DOENTE COM CAPSULITE ADESIVA, OSTEOPOROSE DE CAUSA MEDICAMENTOSA E MIOSITE OSSIFICANTE ASSOCIADA À TERAPÊUTICA COM ETRETINATO

FERNANDO SARAIVA*, MÁRIO RODRIGUES**, ARMANDO MALCATA**,
RUI LEITÃO**, JAIME BRANCO**, TEIXEIRA DA COSTA**
E M. VIANA DE QUEIROZ***

RESUMO

Os autores descrevem o que pensam ser o 1.º caso de associação entre espondilite anquilosante e ictiose congénita (variedade lamelar), num doente com capsulite adesiva bilateral dos ombros, osteoporose de causa medicamentosa e miosite ossificante associada à terapêutica com etretinato.

ABSTRACT

The authors describe what they think is the first case of combined ankylosing spondylitis and congenital ichthyosis of the lamelar variety, in a patient with bilateral adhesive capsulitis of the shoulders, iatrogenic osteoporosis and myositis ossificans associated to etretinate.

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INTRODUÇÃO

A ictiose congénita, uma das alterações inatas da queratinização, subdivide-se em vários quadros patológicos, genética e evolutivamente distintos: ictiose vulgar (autossómica dominante ou ligada ao cromossoma x), ictiose epidermolítica (ou eritrodermia ictiosiforme bolhosa), ictiose associada a degenerescência cerebelosa e hepatosplenomegália, ictiose hystrix e seus sub-tipos, eritrodermia ictiosiforme não-bolhosa e ictiose lamelar. Às duas últimas designações, tidas classicamente como sinónimos (1), correspondem agora características que permitem separar dois quadros distintos (2).

A ictiose lamelar é uma doença rara com carácter autossómico recessivo. Carateriza-se pela existência de espessa descamação hiperqueratósica, por vezes escura, afectando toda a pele. A face está geralmente envolvida, apresentando frequentemente ectropion e deformação dos pavilhões auriculares. Os pelos e cabelos são esparsos. O eritema está ausente ou é ligeiro e os dentes e mucosas não revelam alterações. O desenvolvimento físico e psíquico é normal (1,2,).

Ao contrário da ictiose adquirida, que vem sendo crescentemente apontada como um novo marcador cutâneo das doenças auto-imunes (3 a 8), encontrámos um único caso de associação entre ictiose congénita (variedade vulgar) e doença auto-imune (lupus eritematoso sistémico), na literatura mundial (9). Este facto, compreensível no caso da ictiose lamelar, dada a sua rariedade, não deixa de ser perturbador no que respeita à ictiose vulgar, que tem uma incidência estimada entre 1/250 e 1/320 (10 a 12). Este conjunto de evidências levou-nos a darmos testemunho do seguinte caso clínico:

CASO CLÍNICO

A.O.F., do sexo masculino, de 23 anos de idade, com ictiose lamelar desde o nascimento, foi submetido irregularmente, durante vários anos e até aos 39, a corticoterapia tópica e sistémica, destinada à dermatose. Após os 39 anos, aquela medicação foi substituída por etretinato, na dose de 50 mg/dia, por indicação do Dermatologista.

Há cerca de 7 anos, 6 meses após o início da terapêutica com retinóides, começa a referir plantalgias bilaterais e lombalgias de ritmo inflamatório, associadas a rigidez matinal prolongada. Nos últimos 5 anos, relata a presença de omalgias bilaterais, de ritmo mal definido e impotência funcional, não acompanhadas de sinais inflamatórios locais.

O doente negou artralgias de outra localização, bem como astenia, anorexia, febre, emagrecimento, olho vermelho, diarreia, uretrite, lesões genitais ou orais.

Antecedentes Pessoais: negou alergias, intervenções cirúrgicas ou outras patologias, para além do mencionado na "Doença Actual".

Revisão dos Sistemas:

— Olhos: fotofobia bilateral desde data que não foi precisada; negou ambliopia.

— Aparelho cardiovascular: hipertensão arterial ligeira nos últimos 5 anos, medicada com hidroclorotiazida/amiloride; negou precordialgias ou dispneia de esforço, ortopneia, palpitações, edemas, perdas de conhecimento ou nictúria.

Negou queixas de outros aparelhos ou sistemas.

História Pessoal e Social: alfabetizado; hábitos alcoólicos moderados; sem hábito tabágicos ou medicamentosos (além dos descritos); vive só, com dificuldades económicas, em casa com condições higiénico-sanitárias básicas asseguradas; sem filhos.

Antecedentes Familiares: pais sem consanguinidade; negou sintomatologia semelhante à sua ou outras doenças de incidência e transmissão familiar; mãe de 70 anos e irmã de 39 anos, saudáveis; pai falecido aos 60 anos por cardiopatia que não soube discriminar.

Exame Objectivo:

— Geral: doente vigil, orientado no espaço e no tempo, colaborante; obeso; idade aparente superior à real; pulso: 72 ppmn, amplo, rítmico e regular; pressão arterial: 155/100 mmHg; frequência respiratória: 16 c/mn, regulares; temperatura axilar: 36.5ºC; mucosas coradas e hidratadas; não se palpam adenopatias; marcada descamação cutânea, generalizada, ligeiramente eritematosa e acentuada diminuição da pilosidade (Fig. 1).

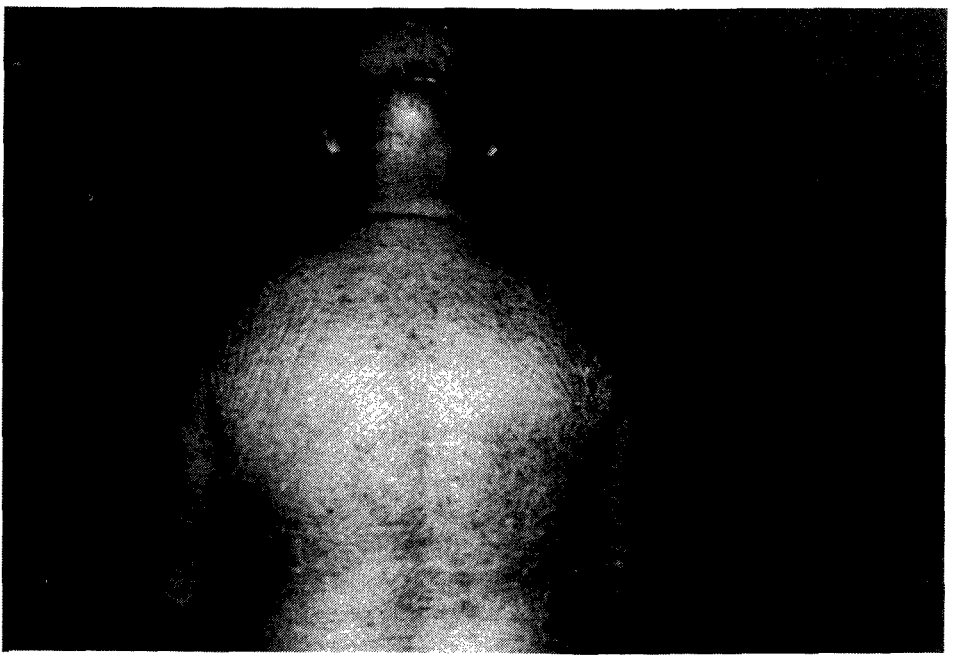

Fig. 1 — Lesões de ictiose lamelar

— Cabeça e Pescoço: alopécia difusa; canal laringo-traqueal centrado e móvel com a deglutição; não se palpam parótidas ou tiroideia aumentadas de volume.
— Tórax: equimóvel e equirresistente; as vibrações vocais transmitem-se normalmente à parede; som claro pulmonar à percussão de ambos os hemitóraxes; murmúrio vesicular conservado bilateralmente; não se ouvem ruídos adventíceos.
— Coração: não se observam pulsações anormais da área précordial; ponto de máxima impulsão no 4.º espaço intercostal esquerdo, na linha médio-clavicular; não se palpam frémitos; S_1 e S_2 puros; não se ouvem sopros, atritos ou arritmias.
— Abdómen: macrosplâncnico; não se observam deformações ou circulação venosa colateral; sinal da onda líquida ausente; depressível e indolor à palpação superficial e profunda, a qual não detecta massas ou visceromegálias; som sub-timpânico ou timpânico à percussão, excepto nas áreas de projecção das vísceras macissas, as quais se encontram dentro dos limites fisiológicos; ruídos hidro-aéreos conservados.
— Membros (exame vascular): não se observam varicosidades ou sinais de flebotrombose; pulsos axilares, humerais, radiais, femurais, popliteus, tibiais posteriores e pediosos, amplos e simétricos.
— Exame Reumatológico: não se observam alterações da marcha; na estática geral do doente, assinala-se um flexo dos joelhos e das ancas a 20º; dor nos movimentos extremos e movimentos limitados de grau 2-3 em 4 (ML_{2-3}) da coluna lombar, com Schober de 10-12 cm; ML_{2-3} dos restantes segmentos do ráquis; ML_{2-3} dos ombros, activos e passivos; cotovelos, punhos e mãos, livres e indolores; ML_{1-2} das coxo-femurais; ML_1 dos joelhos; ML_2 das tíbio-társicas; articulações dos pés livres e indolores.
— Exame Neurológico: reflexos osteo-tendinosos e cutâneos, força e tónus musculares, coordenação motora, sensibilidades táctil, dolorosa e postural e função dos pares craneanos, conservados e simétricos.

Pediram-se os seguintes exames complementares: Hgb 11.5g; GV 3540000/mm^3; GB 9100/mm^3 (58% de neutrófilos, 37% de linfócitos, 2% de eosinófilos, 3% de monócitos e 0% de basófilos); Plaq 320000/mm^3; VS 92mm na 1.ª hora; creat 0.8mg/dl; ureia 37mg/dl; glic 80mg/dl; ác. úr 6.4mg/dl; bil. tot 0.78mg/dl; prot. tot 7.48g/dl; alb 4.0g/dl; $alfa_1$ 0.26g/dl; $alfa_2$ 0.58g/dl; beta 0.98g/dl; gama 1.66g/dl (policlonal); col. tot 240mg/dl; trig 180mg/dl; fosf. alc 48 U/l; TGO 17 U/l; TGP 14 U/l; gama-GT 13 U/l; K 3.96mEq/l; Na 144mEq/l; Ca 9.6mg/dl; P 3.2mg/dl; fact. reum indetectáveis; HLA A2 B12 B35 DR3; calciúria 24 h 107mg; hidroxiprolinúria 24 h 21.3mg; urina II — densidade 1020, hgb vestígios, GV 5/c, GB 2/c e proteinúria, glicosúria e cetonúria ausentes.

Os exames radiológicos convencionais revelaram: ombros — esclerose sub-condral, diminuição da entrelinha articular (mais à direita) e calcificação exuberante ao nível do recesso axilar esquerdo (Fig. 2); bacia — sacroileíte de grau III-IV, esclerose sub-condral, osteofitose e diminuição moderada da

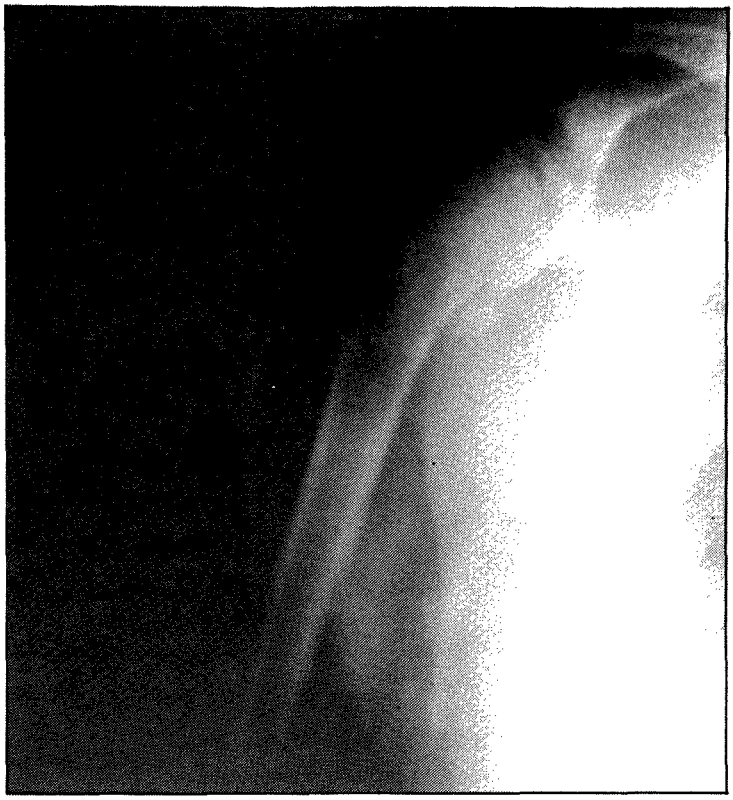

Fig. 2 — Calcificação péri-articular do ombro

entrelinha articular ao nível das coxo-femurais, ossificações volumosas das massas musculares pélvicas (Fig. 3); coluna vertebral — sindesmofitose (Fig. 3) e osteopénia.

A artrografia dos ombros comprovou a existência de capsulite adesiva bilateral (Fig. 4).

A absorciometria bi-fotónica evidenciou uma osteoporose com componente cortical (BMD cerca de 10% abaixo do normal ao nível do colo do fémur) e trabecular (BMD cerca de 12% abaixo do normal ao nível da coluna lombar).

DISCUSSÃO

A presença de sacro-ileíte sintomática e o quadro cutâneo acompanhante, permitiram excluir, na ausência de outras manifestações tais como diarreia, emagrecimento, olho vermelho ou alterações das mucosas, espondiloartropatias sero-negativas ditas secundárias, tais como o síndroma de Reiter, a espondiloartropatia psoriática ou a das doenças inflamatórias do intestino (13), assentando-se definitivamente no diagnóstico de espondilite anquilosante.

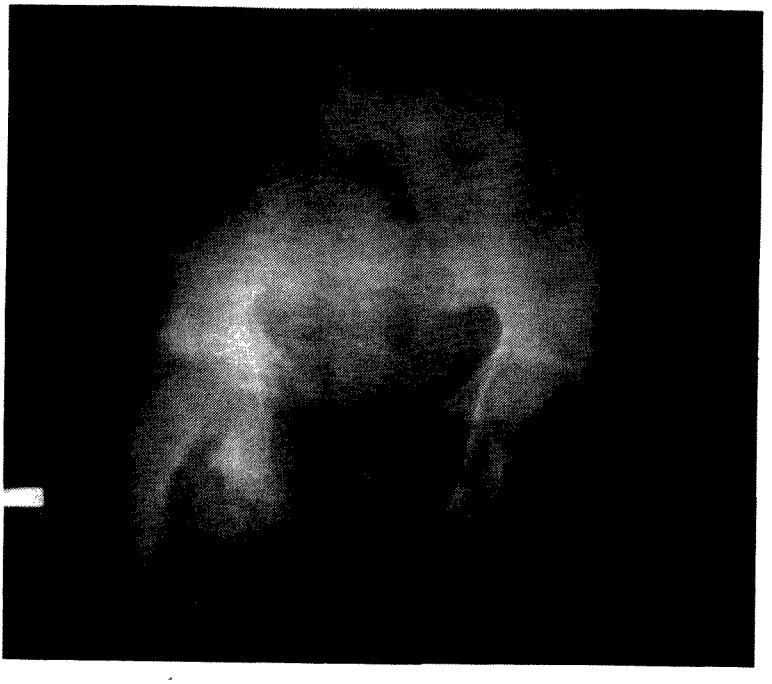

Fig. 3 — Miosite ossificante e sacro-ileíte

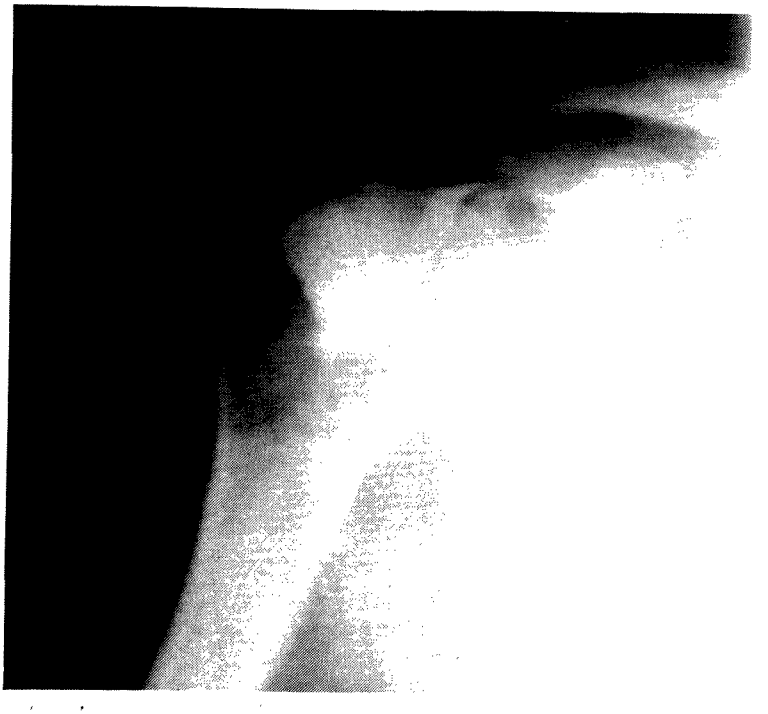

Fig. 4 — Artrografia do ombro típica de capsulite adesiva

Na etiopatogénese da osteoporose, documentada na radiologia convencional e na absorciometria, podem ser implicados quer os corticóides quer os retinóides. De facto, o doente não apresentava estigmas de outras patologias potencialmente osteopenizantes, nomeadamente doenças neoplásicas, endócrinas, renais ou síndromas de má-absorção (14).

Aceitando, com DePalma (15), que qualquer condição que diminua a mobilidade escápulo-humeral, predispõe ao desenvolvimento de capsulite adesiva, não é difícil estabelecer uma relação entre a artrose gleno-humeral, a calcificação péri-articular e a capsulite retráctil (15,16), excluídas outras causas desta afecção, como doenças pulmonares, cardiovasculares, traumatismos ou radiculopatias cervicais (16 a 18).

Quanto à miosite ossificante, ela distingue-se da entesite ossificante da espondilite anquilosante, pelo aspecto grosseiro, disposição espacial e volume das ossificações verificadas no nosso doente (19 a 21). Por outro lado, a ausência de hipercalcémia, hiperfosfatémia, outra conectivite ou doença metabólica associada, permitiu a exclusão de outras causas de calcinose (22). A inexistência de história familiar permitiu excluir a miosite ossificante progressiva, que, como se sabe, apresenta transmissão autossómica dominante. Assim, no nosso caso, a miosite ossificante pôde ser atribuída à terapêutica com retinóides sintéticos (23).

O diagnóstico diferencial da ictiose lamelar faz-se com outras formas de ictiose e com outras variedades de dermatose e é do âmbito da Dermatologia.

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São ambas publicadas trimestralmente (Março, Junho, Setembro e Dezembro) e distribuídas aos Membros da Sociedade e, tanto quanto possível, a Instituições médicas e científicas, nacionais e estrangeiras (Ligas e Centros de Reumatologia e afins; Faculdades de Medicina; Universidades e Centros de Investigação; Sociedades Médicas e Científicas; Hospitais e Serviços Clínicos; Revistas e Jornais Médicos), com permuta de publicações e de planos de investigação e de actividade científica, clínica e social.

A Sociedade agradece os nomes e endereços de Instituições deste tipo existentes no País.

Cônscia de que os problemas criados pelas doenças reumatismais transcendem o âmbito médico e devem também interessar toda a comunidade, a Sociedade distribui o seu »Boletim Informativo» também a Entidades oficiais e particulares, a Meios de Informação (Imprensa TV e Rádio) e a Laboratórios de produtos químicos farmacêuticos, em Portugal.

Gratos pela vossa cooperação, subscrevemo-nos com as mais cordiais saudações.

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Cher(s). Collègue(s) / Monsieur (Messieurs).

La Société Portugaise de Rhumatologie est très heureuse de vous remettre ses publications «ACTA REUMATOLÓGICA PORTUGUESA» (revue de documentation médicale rhumatologique) et le «BOLETIM INFORMATIVO» (bulletin d'information rhumatologique du Pays et de l'Étranger).

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Nous serions très reconnaisants de nous faire parvenir les noms et les adresses de ces Instituitions chez vous.

En vous remerciant d'avance votre coopération, nous vous prions d'agréer l'assurance de nos sentiments les plus distinguées.

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Dear Colleague(s) / Sir(s)

The Portuguese Society of Rheumatology is very good to send you the publications: The «ACTA REUMATOLÓGICA PORTUGUESA» (review of medical documentation) and the «BOLETIM INFORMATIVO» (bulletin on rheumatological information).

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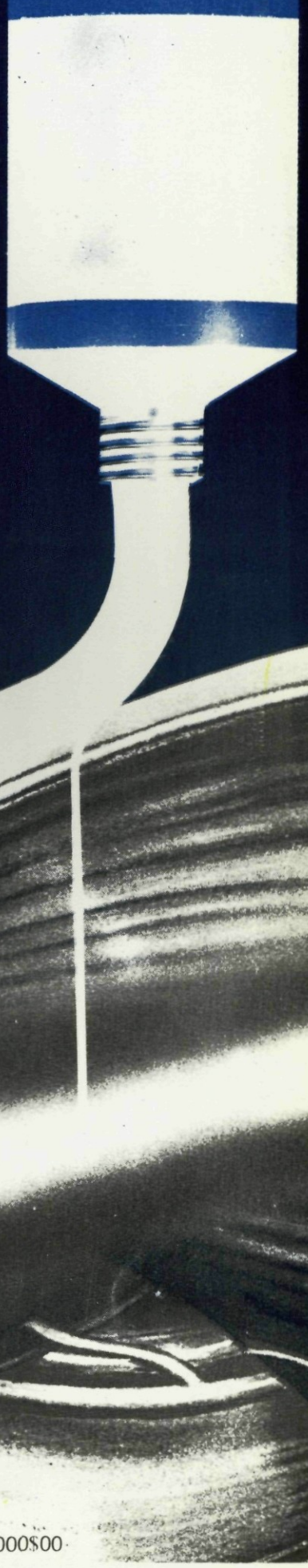

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