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Severe nasal polyposis and its impact on quality of life. The effect of a short course of oral steroids followed by long-term intranasal steroid treatment*

Isam Alobid[1,3], Pedro Benitez[1], Laura Pujols[3], Miguel Maldonado[3], Manuel Bernal-Sprekelsen[1], Antonio Morello[1], Cesar Picado[2], Joaquim Mullol[1,3]

[1] Rhinology Unit, Department of Otorhinolaryngology (ICEMEQ), Hospital Clínic, Universitat de Barcelona, Spain

[2] Department of Pneumology, (ICPCT), Hospital Clínic, Department of Medicine, Universitat de Barcelona, Spain

[3] Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain.

SUMMARY

Objectives: *Nasal polyposis is not a life-threatening disorder but has a great impact on the quality of life. Steroids constitute the first line of treatment of nasal polyps. The aims of this study were to evaluate the quality of life in nasal polyp patients after: (1) a short course of oral steroids; and (2) a long-term treatment with intranasal steroids.*

Methods: *Patients with severe nasal polyps received either oral prednisone (n=60) or no steroid treatment (control group, n=18) for 2 weeks. Patients treated with steroids were also followed-up and evaluated after 12, 24, and 48 additional weeks with intranasal budesonide treatment.*

Results: *Patients with nasal polyps showed worse scores on all SF-36 domains, except for physical functioning, compared to the Spanish general population. After two weeks, patients treated with oral prednisone demonstrated a significant improvement ($p<0.05$) in all impaired QoL domains compared to both control group and baseline. The mental component summary (51.0 ± 1.2, $p<0.05$) and physical component summary (51.0 ± 0.9, $p<0.05$) were improved compared to both control group and baseline. The improvement of all SF-36 domains was sustained by intranasal budesonida ($p<0.05$) after 12, 24, and 48 weeks. Nasal obstruction, sense of smell, and polyp size also improved after both the oral short course and the intranasal long-term steroids treatment ($p<0.05$).*

Conclusion: *These results suggest that the treatment with a short-course of oral steroids improves the quality of life of patients with severe nasal polyps and that this effect is maintained by a long-term treatment with intranasal steroids.*

Key words: asthma, nasal polyposis, quality of life, SF-36 questionnaire, steroids

INTRODUCTION

Nasal polyposis (NP) is a chronic inflammatory disease involving the nasal and paranasal sinuses mucosa [1]. NP has been associated with different systemic and respiratory diseases such as cystic fibrosis, rhinitis, and asthma with or without aspirin sensitivity [2].

The management of NP has been the topic of frequent controversial debates for many decades. Most authors agree on the fact that management of NP should be primarily based on a medical approach to be completed by surgical procedures only in the case of drug failure [3]. Treatment with oral or intranasal steroids has been shown to reduce polyp size, relieve symptoms, and reduce recurrence rates after surgery. Short courses of systemic steroids may be also used mainly in moderate to severe polyps to induce a rapid polyp size reduction facilitating the ability of the intranasal steroids to gain access to the polypoid tissue [4]. Resorting to surgical procedures should not be envisaged before a trial is conducted of dual steroid therapy under a regimen of strict compliance to treatment [5].

A global evaluation of PN must include, together with nasal endoscopy, symptoms assessment, and CT scan, the measurement of quality of life (QoL). Specific questionnaires are restricted to a particular disease, a selected population, or a specific function or problem. Several specific instruments for patients with chronic sinusitis have been developed such as Rhinosinusitis Disability Index, Chronic Sinusitis Survey Score,

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Table 1. Characteristics of patients with nasal polyposis.

	Group A			Group B		
	N	Age (yr)	Gender (M/F)	N	Age (yr)	Gender (M/F)
All patients with nasal polyposis	60	50 ± 1.8	39/21	18	49 ± 3.4	12/6
Nasal polyposis without asthma	21	53 ± 3.4	14/7	5	48 ± 7.2	4/1
Nasal polyposis with asthma:	39	49 ± 2.2	25/14	13	52 ± 3.9	8/5
- aspirin-tolerant	22	49 ± 3.2	15/7	8	52 ± 6.0	5/3
- aspirin-sensitive	17	48 ± 2.9	10/7	5	51 ± 4.6	3/2

Group A, patients with nasal polyps treated with a short course of oral prednisone followed by long-term intranasal budesonide. Group B, patients receiving no oral or intranasal steroids (control group). M/F, male/female.

and SinoNasal Outcome Test-16. Generic questionnaires are applicable to all health conditions and they allow comparing QoL in different diseases as well as healthy and diseased subjects. The Medical Outcome Study Short Form-36 (SF-36) is the most widely used generic instrument [6]. The Spanish version of the SF-36 has been previously used to measure QoL, showing a good reproducibility and validity [7,8].

The two main aims of this study were: (1) to evaluate the QoL outcome after a short course of oral steroids compared to a non-treated control group; and (2) to assess the long-term effect of intranasal steroids on QoL.

METHODS

Study population

Seventy-eight patients with nasal polyps were included in this prospective study from February 1999 to July 2003. Sixty patients were included in the study group (group A) and 18 in the control group (group B) (Table 1). The mean age was 50 ± 1.6 years (ranging from 22 to 84 years), and 27 patients (35%) were female. There were no differences between group A and group B. All patients had severe NP (main score of 2.7 in the Lildholdt classification [9]) and were examined by the same otorhinolaryngologist at the Department of Otolaryngology, Hospital Clinic of Barcelona. Approval for this study was obtained from the Ethic's Committee of our institution and a signed informed consent was obtained from all patients.

Inclusion and exclusion criteria

The diagnosis of NP was based on the following criteria: 1) the visualization of bilateral polyps under nasal endoscopic examination, and 2) the bilateral opacification of paranasal sinuses and nasal cavities on computed tomography (CT) scans. Asthmatic patients were evaluated by the same pneumologist of our institution and the diagnosis of aspirin intolerance was made on the basis of a clear-cut history of asthma attacks precipitated by non-steroidal antiinflammatory drugs (NSAIDs). Aspirin sensitivity was tested by nasal challenge with lysine acetylsalicylic acid (L-ASA, 25 mg) only in those asthmatic patients with unknown or doubtful diagnostic [10]. Asthmatic patients did not modify their treatment during the study. Patients with antrochoanal polyps and cystic fibrosis were excluded from the study. Patients with contraindication to steroids were also excluded.

Study design

After a 4-week washout period of both oral and intranasal steroids (week 0), 60 patients received oral prednisone (group A: 30 mg daily for 4 days, followed by a two-days reduction of 5 mg), while 18 patients of control group (group B) received no steroid treatment during 2 weeks (w2) (Figure 1). One fourth of all patients (20) were randomized to control group but 2 patients were dropped-out of the study due to loss of follow-ups. Only 2 patients (2.6%) with NP were in treatment with oral steroids and 17 patients (21.8%) in irregular treatment with intranasal steroids. However, in the majority of experimental and trail studies investigating NP is considered sufficient a 4 weeks of washout for both oral and intranasal steroids. Three other follow-up evaluations were performed for group A at 12 (w12), 24 (w24), and 48 (w48) weeks after intranasal budesonide (400 μg/twice a day). Nasal obstruction, loss of sense of smell, polyp size, and QoL were all scored at w0, w2, w12, w24, and w48. Patients of group B were only evaluated at w0 and w2. Because of the concern of the ethics committee on keeping patients more than 6 weeks without known effective treatment, patients of the control group were not further evaluated. At w0, a total of 12 patients had a previous nasosinusal surgery but there were no differences on QoL between operated and non operated patients.

Quality of life (SF-36) assessment

The SF-36 questionnaire consists of 36 self-administered ques-

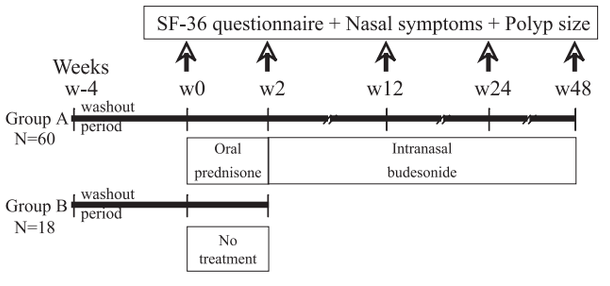

Figure 1. Study algorithm. Group A, patients with nasal polyps treated with a short course of oral prednisone followed by long-term intranasal budesonide. Group B, patients receiving no oral or intranasal steroids (control group).

tions that cover eight health domains: physical functioning, role physical, bodily pain, and general health, vitality, role emotional, social functioning, and mental health. Scale scores range from 0 to 100 and higher scores indicate better QoL. In addition, the physical component summary (PCS) and the mental component summary (MCS) scores were calculated.

Nasal symptom scores

Nasal obstruction and loss of the sense of smell were recorded. The severity of these symptoms was assessed and scored as follows: 0, no symptom; 1, mild but not troublesome symptom; 2, moderate symptom somewhat troublesome but not enough to interfere with daily activity or sleep; and 3, severe and troublesome symptom that interferes with daily activity or sleep.

Polyp size score

Using endoscopy, polyp size was scored from 0 to 3 for each nasal cavity (Lildholdt classification [9]): 0, no polyps; 1, mild polyposis (small polyps not reaching the upper edge of the inferior turbinate); 2, moderate polyposis (polyps between the upper and lower edges of the inferior turbinate); 3, severe polyposis (large polyps reaching the lower edge of the inferior turbinate).

Statistical Analysis

Data analysis was performed with the statistical package SPSS 10.0 for Windows (SPSS Inc, Chicago, Ill). The data are presented as mean ± SEM (standard error of the mean). A p value of less than 0.05 was considered statistically significant. All data was assessed for normal distribution and the Bonferroni correction for multiple comparisons was used. Unpaired Student's t test was used to compare the SF-36 scores of nasal polyp patients with the Spanish general population. Population-based norms have been obtained from 9,984 individuals of whom 51.8% were females [7]. There was no significant difference on the mean age between patients of our study and the Spanish general population. QoL scores, after treatment, were compared to baseline scores by 2-tailed paired Student's t test and differences between groups were assessed using the Student's unpaired t test. Pearson correlation coefficients were used to examine the association between QoL scores and gender, age, and nasal symptoms. For each SF-36 scale, Cronbach's · coefficient was calculated to estimate internal consistency and a minimum coefficient of 0.7 is recommended.

RESULTS

Quality of life (SF-36) assessment

Before treatment (w0) and in comparison to the Spanish general population [6], patients with NP had significantly worse QoL scores in all SF-36 domains, except for physical functioning (Figure 2). The MCS (39.4 ± 1.9, $p<0.05$) was significantly lower than the PCS (46.5 ± 1.9), keeping in mind that the Spanish general population has similar values for both MCS (79.7) and PCS (78.8), suggesting that NP impaired mental health more than physical health. At w0, there were no significant differences on SF-36 domains between patients of group A and group B. Males and females scored similarly in the SF-36 domains with no differences respect to the Spanish general population. Age, gender, nasal symptoms, and polyp size scores did not statistically correlate to SF-36 scores.

Compared with w0, patients treated with oral steroids (group A) demonstrated a significant improvement at w2 in all domains of SF-36 (Figure 2), as well as in MCS and PCS (Table 2), compared to control group (group B), reaching the QoL levels of the

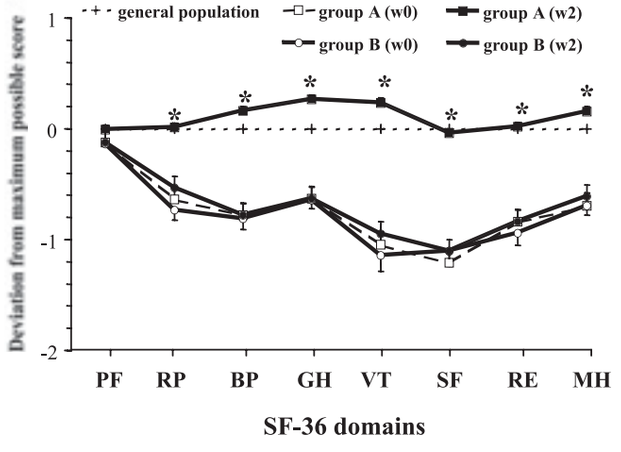

Figure 2. Quality of life improvement in patients with nasal polyposis receiving oral prednisone during 2 weeks (group A) compared to control group (group B). Physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH). Student's t test, * $p<0.05$, 2 weeks (w2) of treatment compared to baseline (w0).

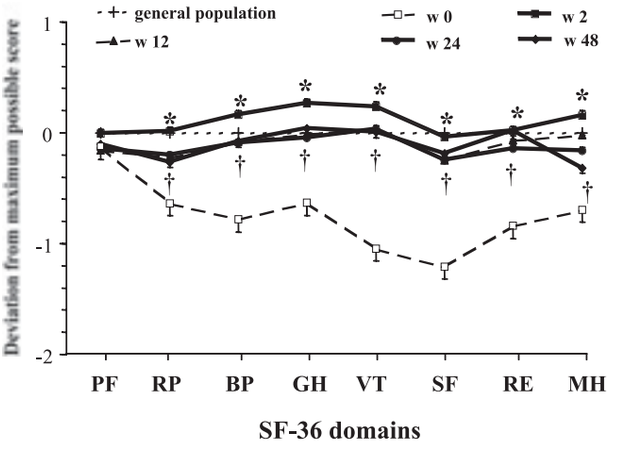

Figure 3. Quality of life improvement in patients with nasal polyposis receiving oral and intranasal steroids (group A). Physical functioning (PF), role physical functioning (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional functioning (RE), and mental health (MH). Student's t test, * $p<0.05$, 2, 12, 24, and 48 weeks of treatment compared to baseline (w0) and † $p<0.05$, 12, 24 and 48 weeks compared to 2 weeks (w2).

Table 2. Physical and mental component summaries of asthmatic and non-asthmatic patients with nasal polyposis at baseline and after 2, 12, 24, and 48 weeks of treatment.

		Physical component summary			Mental component summary		
		All NP patients	Without asthma	With Asthma	All NP Patients	Without asthma	With asthma
Baseline (w0)	group B	45.8±1.8	47.6±3.4	44.8±2.2†	39.1±1.5	39.9±3.0	38.5±1.4†
	group A	46.5±1.9	48.2±2.1	45.5±3.4†	39.4±1.9	41.1±2.1	38.6±3.0†
2 weeks (w2)	group B	46.3±1.9	48.3±3.0	44.7±2.1†	39.4±1.8	40.6±2.6	38.9±1.7†
	group A	51.0±0.9*¶	51.0±1.1*¶	50.9±1.5*¶	51.0±1.2*¶	52.2±1.4*¶	50.2±1.8*¶
12 weeks (w12)		49.3±1.3*‡	50.1±1.4*‡	48.8±2.4*‡	49.5±1.3*‡	50.5±1.6*‡	48.9±2.0*‡
24 weeks (w24)		48.9±1.2*‡	50.0±1.4*‡	48.3±2.3*‡	48.7±1.4*‡	48.9±1.8*‡	48.5±1.6*‡
48 weeks (w48)		49.1±1.3*‡	50.1±1.6*‡	49.2±2.4*‡	48.7±1.2*‡	47.5±1.6*‡	49.9±1.6*‡

Group A, patients with nasal polyps treated with a short course of oral prednisone followed by long-term intranasal budesonide. Group B, patients receiving no oral or intranasal steroids (control group). Student's t test: * $p<0.05$, w2, w12, w24 and w48 compared to w0; † $p<0.05$, asthmatic compared to non-asthmatic patients; ¶ $p<0.05$, group A compared to group B; and‡ $p<0.05$, w12, w24, and w48 compared to w2.

Table 3. Nasal obstruction, loss of the sense of smell, and polyp size scores at baseline and after 2, 12, 24 and 48 weeks of treatment.

		Nasal obstruction	Loss of smell	Polyp size
Baseline (w0)	Group B	2.3±0.1	2.4±0.1	2.8±0.1
	Group A	2.4±0.1	2.3±0.1	2.7±0.1
2 weeks (w2)	Group B	2.3±0.1	2.3±0.1	2.8±0.1
	Group A	1.3±0.1*¶	1.7±0.1*¶	1.7±0.1*¶
12 weeks (w12)		1.5±0.1*	1.9±0.1*‡	1.8±0.1*‡
24 weeks (w24)		1.5±0.1*‡	2.0±0.1*‡	2.0±0.1*‡
48 weeks (w48)		1.7±0.1*‡	1.9±0.1*‡	2.2±0.1*‡

Group A, patients with nasal polyps treated with a short course of oral prednisone followed by long-term intranasal budesonide. Group B, patients receiving no oral or intranasal steroids (control group). Student's t test; * $p<0.05$, w2, w12, w24, and w48 compared to w0; ¶ $p<0.05$, group A compared to group B; and ‡ $p<0.05$, w12, w24 and w48 compared to w2.

Spanish general population, while patients from group B had similar SF-36 domains at w2. Although some worsening of the QoL was observed at w12, w24, and w48 compared to w2, treatment with long-term intranasal budesonide maintained SF-36 domains at the level of the Spanish general population and markedly higher than baseline scores (Figure 3).

At w0, asthmatic patients with NP had worse scores of QoL ($p<0.05$) than non-asthmatic patients in role physical, body pain, and vitality. Also before treatment asthmatic patients showed lower PCS and MCS than non-asthmatic patients ($p<0.05$) (Table 2). At w2, PCS and MCS significantly improved after oral steroids in both asthmatic and non-asthmatic patients. After intranasal steroids, both PCS and MCS worsened compared to those from patients treated with oral steroids but still keeping at the level of the general population. Both oral and intranasal steroids improved QoL without differences between asthmatic and non-asthmatic patients.

Analysis of internal consistencies for all SF-36 domains showed a Cronbach's · value higher than 0.7 (varied from 0.73 to 0.88) except for physical functioning (0.60).

Nasal symptom scores

The mean duration time of nasal symptoms was 8.8 ± 1.1 years. Patients scored nasal obstruction and loss of the sense of smell as the major nasal complaints (Table 3), while other nasal symptoms were much less frequent and discomforting. At w0, patients of group A and group B had similar nasal symptoms, but at w2 patients of group A had significant improvement in nasal obstruction and loss of the sense of smell compared to group B patients and compared to w0. At w12, w24, and w48 nasal symptoms were slightly increased compared to w2 but remained significantly better compared with w0 (Table 3).

At w0, asthmatic patients with nasal polyps had higher scores of nasal obstruction (2.6 ± 0.1) and loss of the sense of smell (2.5 ± 0.1) than non-asthmatic patients (2.1 ± 0.2 and 2.0 ± 0.1 respectively) ($p<0.05$). At w2, w12, w24, and w48, asthmatic and non-asthmatic patients scored similar improvement in nasal obstruction and loss of sense of smell.

Polyp size score

At w0, patients of group A and group B had similar polyp size

score, but at w2 patients of group A had significant low polyp size score compared to group B and compared to w0. At w12, w24, and w48 after intranasal steroids, polyp size was slightly increased compared to w2 but maintained significantly reduction of polyp size compared with w0 (Table 3). Asthmatic and non-asthmatic patients of group A had similar polyp size score before treatment and at w2, w12, w24, and w48.

No significant differences in QoL, nasal symptoms, and polyp size between aspirin-tolerant and aspirin-sensitive asthmatics were observed before treatment (w0) and after a short course of prednisone (w2) or long-term intranasal budesonide (w12, w24, and w48).

Recourse to surgery could not be avoided in 10 patients (17 %) of group A at the end of study because of steroid treatment failure. These patients showed no significant improvement of nasal symptoms and polyp size scores and were finally operated. There was not a predominance of patients with asthma or aspirin sensitivity in those patients who underwent endoscopic sinus surgery.

DISCUSSION

The main findings of our study showed that: 1) a short course of oral steroids improved the QoL outcomes of patients with NP reaching those of the general population; and 2) long-term intranasal steroids maintained this improved effect on the QoL.

Our group has recently reported that QoL in patients with NP is impaired compared to the Spanish general population, the mental health being more impaired than the physical health [11]. Previously, Radenne et al.[12] investigated the impact of NP demonstrating that nasal polyps impair QoL in all SF-36 domains. Using the SF-36, other studies have also demonstrated that chronic rhinosinusitis has a considerable impact on all SF-36 domains except for physical functioning and compared to a healthy population [13-16]. Patients with NP have lower scores in all SF-36 domains except for physical functioning and general health than patients with coronary artery disease, asthma, and chronic obstructive pulmonary disease [8].

There is a lack of controlled studies investigating the effect of oral steroids on nasal symptoms and QoL in patients with nasal polyps. In the present study, a short course of oral steroids caused a significant improvement in all domains of SF-36. Long-term treatment with intranasal steroids maintained this improvement at the level of the Spanish general population. Although the reduction of polyp size is not really important, the clinical improvement especially the mental health is more significant.

Radenne et al. [12] showed that intranasal steroids improved the symptoms and the QoL in patients with NP especially in body pain, general health, vitality, social functioning, and mental health domains. Other authors have also found that patients with chronic sinusitis present a significant improvement in QoL after sinus surgery, reaching the general population levels [13,14]. In a recent study we have reported that both medical (combined oral and intranasal steroids) and surgical (endoscopic sinus surgery followed by intranasal steroids) treatments led to similar long-term effects in improving QoL [17].

Before treatment, the two most disabling symptoms in nasal polyp patient were nasal obstruction and loss of the sense of smell. No correlation was observed between impaired QoL and nasal symptoms. All nasal symptoms clearly improved after oral steroid treatment and intranasal steroids maintained this effect. After two weeks of oral steroids, Van Camp and Clement [18] showed a clear improvement in nasal symptoms especially for nasal obstruction and loss of the sense of smell. In the last decade, intranasal steroids have gained acceptance as an alternative treatment of surgery for NP. Holmberg et al. [19] showed that intranasal fluticasone or beclomethasone are effective in reducing nasal symptoms when compared to placebo. Combined oral and intranasal steroids seem to be effective to treat NP by improving the sense of smell, nasal obstruction, and other nasal symptoms [4]. Jankowski and Bodino showed that nasal obstruction was a major complaint of NP patients and the long-lasting correction of olfactory dysfunction can be achieved through the combination of nasalization and low dose of nasal steroids [20,21].

In our study, short course of oral steroids resulted in a significant reduction of polyp size, and polyp reduction was maintained by long-term intranasal steroid. van Camp and Clement [18] reported that 72% of the patients with NP showed subjective improvement due to the involution of polyps in the nasal cavity after two weeks of oral steroids. Many studies have demonstrated that intranasal steroids are more effective than placebo in polyp size reduction [5,22].

The authors have previously reported that asthmatic patients present a higher nasal symptom score and worse QoL for both PCS and MCS than non-asthmatic patients especially on role physical, body pain and vitality [11]. However, asthmatic and non-asthmatic patients had similar nasal symptoms, polyp size, and scored similar QoL domains for both PCS and MCS after oral steroids, and these effects were maintained after long-term intranasal steroid therapy. Radenne et al. [12] also reported greater impairment of QoL when NP was associated with asthma showing that physical functioning, role physical, role emotional, vitality, and body pain scores were significantly lower in asthmatic than in non-asthmatic patients. However, Gliklich and Metson [13] reported that the presence of asthma was not predictive of a poor outcome in patients with chronic sinusitis. Winstead and Barnett [14] also demonstrated that asthma had an adverse impact on vitality and general health compared with rhinosinusitis alone, but no significant differences in postoperative SF-36 scores from patients with rhinosinusitis alone were found.

Few studies have been conducted to assess the impact of aspirin sensitivity on QoL in patients with nasal polyps. Recently we have demonstrated that aspirin sensitivity has no further negative impact on QoL [11]. In the present study, no significant differences in nasal symptoms, polyp size, and QoL between

aspirin-tolerant and aspirin-sensitive asthmatics were found before and after short course of oral steroids or long-term intranasal steroid treatment.

In conclusion, these results suggest that NP has a considerable impact on QoL, the treatment with a short-course of oral steroids markedly improve the QoL of patients with nasal polyps and that this effect is maintained by a long-term treatment with intranasal steroids.

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Joaquim Mullol
Department of Otorhinolaryngology
Hospital Clínic i Universitari
c/ Villarroel, 170
Barcelona 08036
Spain

Tel: 34- 932 279 872
Fax: 34- 932 275 454
E-mail: jmullol@clinic.ub.es