

CLINICAL, EPIDEMIOLOGICAL AND COST ASPECTS OF CONTACT LENS RELATED INFECTIOUS KERATITIS IN BELGIUM: RESULTS OF A SEVEN - YEAR RETROSPECTIVE STUDY

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ABSTRACT

Aim: Evaluation of the clinical, epidemiological and cost aspects of contact lens related infectious corneal ulcers requiring hospitalisation.

Methods: A retrospective analysis was performed on the files of patients hospitalised for contact lens induced corneal ulcer in the eight Belgian University Hospitals over a seven-year period (January 1997 until December 2003). For all hospitalised patients registration of the diagnosis is compulsory using the International Code of Diagnostics (ICD-9).

Results: 107 patients with contact lens related corneal ulcer were included. The great majority, 99 subjects, used soft contact lenses, of which 9 were disposables, 73 planned replacement and 17 conventional lenses. Only 6 patients were night and day wearers. Three patients used daily disposable lenses. The most frequently cultured organisms were *Pseudomonas* and other Gram-negative germs (70 %) and *Acanthamoeba* (16 %). The majority (77 %) of the corneal ulcerations were localised centrally which resulted in an average visual loss of 4 lines. In 16

patients a corneal graft was performed and one eye had to be eviscerated.

Conclusion: Despite important technological improvements in contact lens materials and care systems, the problem of infectious ulceration has all but disappeared. On the contrary, during the study period, the number of patients hospitalised increased from 5 in 1997 to 22 in 2003, which is only partially explained by the increasing prevalence of lens wearers: 3,5 % of the Belgian population in 1995 and 6,5 % in 2003.

RÉSUMÉ

Objectif: Etude clinique, épidémiologique et financière des ulcères cornéens causés par le port de lentilles de contact ayant nécessité une hospitalisation.

Méthodes: Une analyse rétrospective des dossiers des patients hospitalisés pour ulcères cornéens induits par le port de lentilles de contact a été réalisée sur une période de 7 ans (janvier 1997 à décembre 2003) dans les huit hôpitaux universitaires belges. Tous les patients hospitalisés sont obligatoirement enregistrés dans le code officiel de diagnostique (ICD-9).

Résultats: Cent et sept patients avec ulcères cornéens liés au port des verres de contacts ont été inclus dans cette étude. Nonante-neuf personnes utilisaient des lentilles souples, jetables dans 9 cas, à remplacement fréquent dans 73 cas et conventionnelles dans 17 cas. Seulement 6 patients portaient

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des lentilles jour et nuit. Trois patients portaient des lentilles journalières. Les organismes les plus fréquemment trouvés en culture étaient des *Pseudomonas* et autres Gram-négatifs (70%) et des *Acanthamoeba* (16%). La plupart des ulcères cornéens avaient une localisation centrale (77%), entraînant une diminution moyenne de l'acuité visuelle de 4 lignes. Seize patients ont reçu une greffe de cornée et un œil a été éviscéré.

Conclusions: Malgré les importants développements technologiques des matériaux et des produits d'entretien des lentilles de contact, le problème d'ulcères infectieux n'a pas disparu. Au contraire, pendant la période de l'étude le nombre de patients hospitalisés est passé de 5 en 1997 à 22 en 2003, ce qui ne peut s'expliquer que partiellement par l'augmentation du nombre de porteurs de verre de contact qui était de 3.5% de la population belge en 1995 et de 6.5% en 2003.

SAMENVATTING

Doel: Studie van de klinische, epidemiologische en financiële aspecten van contactlens gerelateerde corneale ulcera die hospitalisatie vereisen.

Methode: Een retrospectieve analyse werd uitgevoerd op de dossiers van de patiënten die gehospitaliseerd werden omwille van contactlens geïnduceerde corneale ulcera in de acht Belgische universitaire ziekenhuizen over een 7-jarige periode (januari 1997 tot en met december 2003). Bij alle gehospitaliseerde patiënten bestaat er een verplichte registratie van de diagnose door middel van de Internationale code van de diagnostiek (ICD-9).

Resultaten: 107 patiënten met contactlens gerelateerde corneale ulcera werden bestudeerd. De grote meerderheid, namelijk 99 personen, droegen zachte contactlenzen, waarvan 9 wegwerplenzen, 73 frequent vervanglenzen en 17 conventionele lenzen. Slechts 6 patiënten waren dag-en-nacht dragers. Er waren 3 patiënten met daglenzen. De meest frequent gekweekte organismen waren *Pseudomonas* en andere Gram-negatieve kiemen (70 %) en *Acanthamoeba* (16%). De meeste corneale ulcera (77 %) hadden een centrale lokalisatie en dit leidde tot een gemiddelde visusdaling van 4 lijnen. Bij 16 patiënten werd een corneatransplantatie uitgevoerd en 1 oog werd geëviscereerd.

Conclusie: Ondanks belangrijke technologische verbeteringen op gebied van contactlensmaterialen en onderhoudssystemen, is het probleem van infectieuze ulcera helemaal niet verdwenen. Integendeel, tijdens de studieperiode liep het aantal gehospitaliseerde patiënten op van 5 in 1997 tot 22 in 2003, wat slechts gedeeltelijk kan verklaard worden door de toegenomen prevalentie van contactlensdragers:

van 3,5 % van de Belgische bevolking in 1995 naar 6,5 % in 2003.

KEY WORDS

corneal ulcer, contact lens

MOTS-CLÉS

ulcère cornéen, lentille de contact

INTRODUCTION

Despite the growing success of refractive surgery, contact lenses remain an important option for correcting refractive errors. There is ongoing research into the development of new lens materials and care systems; there is a marked tendency towards shorter renewal periods. Recent studies however continue to report on the occurrence of complications in lens wearers, the most severe and vision-threatening of which is infectious keratitis (2,4,8,17). Several surveys have been conducted to investigate potential risk factors: soft contact lenses, bad compliance and day and night wear are considered as the most important risk factors (1,5,9,11,12,13).

Concern about contact lens related complications in Belgium has increased since 1998; from then on contact lenses were freely sold in commercial spaces, like drug stores and supermarkets, without any supervision of a contact lens specialist. As ophthalmologists we think that this has led to trivialisation of contact lens wear with the general public so that contact lenses are no longer perceived as medical appliances that can interfere with the health of the wearers' eyes (14). Ophthalmologists in the field of contactology only had anecdotal evidence that the frequency of microbial keratitis due to contact lens use might be increasing. To either confirm or deny this perception we decided to do a retrospective study on clinical, epidemiological and cost aspects of patients hospitalised in the Belgian university hospitals for infectious corneal ulceration associated with contact lens use.

MATERIALS AND METHODS

A retrospective survey on hospitalised corneal ulcers through the years 1997 up to 2003 was conducted in the eight Belgian university hospitals; complications of this severity are most likely admitted at a hospital of this level and we were assured of a good cooperation for obtaining information. We may have missed a few cases hospitalised in other clinics, but most hospitals are not keen on having these patients who need intensive treatment and daily follow-

up, and who occupy a bed for several days (and sometimes weeks).

We could only include the hospitalised patients in our study: in Belgium registration of the diagnosis is obligatory for each hospitalised patient using the ICD-9 codes, this obligation does not exist for patients treated on an ambulatory basis. Based on the ICD-9 codes we could retrospectively trace the medical files of the patients who had been hospitalised for corneal ulceration (codes 370.00 to 370.55). Because no coding for contact lenses had been used, a large number of files were generated and each of them had to be checked manually to see whether or not the ulceration was contact lens related. Only the records of the ulcerations related to cosmetic contact lens wear were retained. The following data were collected from each chart: university centre, date of hospitalisation, length of hospitalisation, patient age and sex, residence, general and ophthalmologic history, type of contact lens used, wearing schedule (daily wear, continuous wear), corneal localization of the ulcer, microbiological culture (corneal scrapings, contact lenses, lens containers and/or contact lens fluids), type of infectious agent, treatment, visual outcome, residual injury and whether or not the patient underwent surgery. Outpatient charts were consulted to determine visual acuity in the affected eye at the last visit and to obtain information on any surgical procedures. If data were incomplete, individuals were followed-up by telephone inquiries. Apart from the clinical information we also collected the financial data linked with the hospitalisation period. To obtain these records, we worked together with the invoice services of the university centres. These data included: "hotel" expenses, medical fees and costs of technical examinations, pharmaceutical costs and personal extras. The repartition was calculated between the amount of costs covered by the Belgian public health insurance and the amount paid by the patient. For one patient these data were untraceable. Information on the number of contact lens wearers in Belgium, with information on the profile of the lens wearers, was obtained through FADICON, the Federation of contact lens producers and distributors in Belgium. (FADICON 2004, unpublished data)

RESULTS

One hundred and seven eyes were identified for analysis during the study period of 7 years. The age of the patients ranged from 13 to 77 years (mean $28,8 \pm 13,9$ years). Female to male ratio was 1,5:1 (65 women and 42 men).

Seventy-six patients had no relevant medical history, 2 suffered from chronic obstructive pulmonary disease, 4 had arterial hypertension, 3 diabetes mellitus, 2 thyroid gland pathology and 13 had an allergic constitution, of which 2 with chronic sinusitis. There were no antecedents of ocular allergy. Concerning the oph-

thalmologic history: 3 had a penetrating keratoplasty, 1 patient had a congenital glaucoma; 1 patient had undergone radial keratotomy 32 years before; 6 patients were hyperopic and 1 was pseudophakic; all other patients (100) had myopia.

The numbers of contact lens related ulcerations presented an increase in the course of the study period: 5 hospitalisations in 1997, 9 in 1998, 12 in 1999, 17 in 2000, 22 in 2001 and remaining at that level in 2002 and 2003. The distribution of the hospitalised cases over the different university centres is shown in Figure 2.

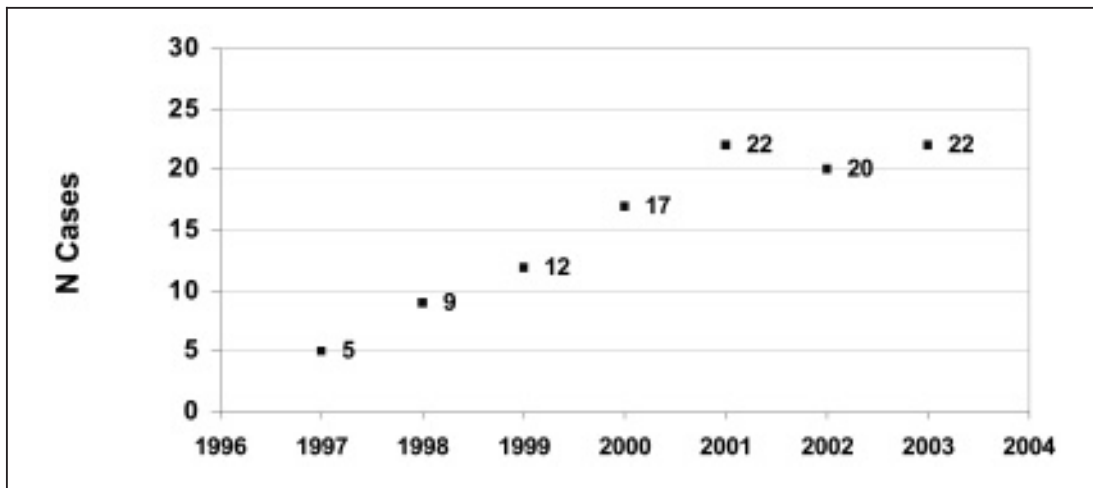


Fig 1. Number of hospitalised contact lens related ulcers, period 1997 - 2003.

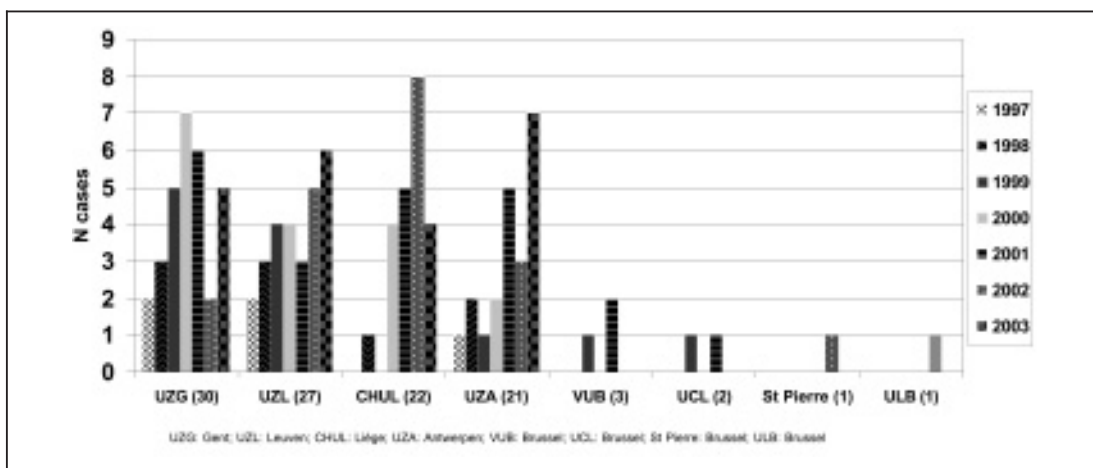


Fig 2. Number of hospitalised contact lens related corneal ulcers at the different university centres.

Table 1: Number of hospitalised contact lens related ulcers by lens type. (N=107)

	1997	1998	1999	2000	2001	2002	2003	Total (%)
Rigid Gas-Permeable	3	3	0	0	0	1	1	7%
Soft Conventional	2	2	2	3	5	3	0	16%
Soft Montly	0	2	8	14	15	15	16	65%
Soft Two-weekly	0	0	1	0	1	0	0	3%
Soft Weekly	0	2	1	0	1	0	2	6%
Soft Daily	0	0	0	0	0	1	2	3%
Total	5	9	12	17	22	20	22	100%

Ninety-nine patients were soft contact lens users: 9 used disposables (weeklies and dailies), 73 planned replacement lenses and 17 lenses of the conventional type. Eight of the hospitalised cases wore rigid gas-permeable lenses; there were no polymethacrylate lenses. The cases of contact lens associated keratitis, distributed among the subgroups of wearers, are shown in Table 1. Six patients were using their lenses in overnight wear as intended in their weekly renewal scheme; another 5 patients (with monthly replacement) admitted sleeping with their lenses although it was not recommended. One person wore the daily disposable lenses for several days.

Ulceration involved almost as many right (55) as left (52) eyes. Seventy-seven per cent (82 out of 107) of the hospitalised contact lens related corneal ulcerations were central i.e. in the pupillary area, the remaining 23 % (25 out of 107) were peripheral.

Microbiological cultures were done in 101 of the cases: samples could be taken from corneal scrapings or conjunctival swabs, from contact lenses, storage cases and/or contact lens fluids. Culture results were positive in 90 cases, including 2 cases of fungal keratitis and 16 Acanthamoebic infections. Eleven of the cultures (10,9 %) showed no growth, one fourth showed (23,4 %) polybacterial infections. Cultures revealed mostly Gram-negative germs as causative agents (68,3 %): *Pseudomonas aeruginosa* in 54 cases, *Serratia marcescens* in 16 cases and *Klebsiella oxytoca* in 10 cases (Table 2).

At the end of the study period all ulcers had healed and visual outcome was stable. In 80 % of patients permanent corneal scarring occurred. Final mean loss of visual acuity was 4

Table 2: Results of bacteriological culture in hospitalised contact lens related corneal ulcers (N = 101).

Gram negative bacteria		68.3%
<i>Pseudomonas aeruginosa</i>	54	
<i>Serratia marcescens</i>	16	
<i>Klebsiella oxytoca</i>	10	
Others	17	
Gram positive bacteria		8.9%
Gram positive cocci	9	
Parasite		15.8%
<i>Acanthamoeba</i>	16	
Fungi		2.0%
<i>Candida albicans</i>	2	
Negative culture		10.9%

lines (range 0 to 10 lines; median of 4 lines). Sixteen eyes underwent penetrating keratoplasty and one eye infected by *Acanthamoeba* had to be eviscerated.

Another aim of the study was to calculate the financial burden for each hospitalisation due to contact lens related corneal ulceration in the period from January 1997 up to December 2003. We obtained the financial data from the invoice departments of the university hospitals. "Hotel" expenses cover the nursing and caring costs, and fixed fees for biological laboratory tests and urgent pharmaceutical needs. Medical fees and costs contain the doctor's remuneration, fixed fees for microbiology, for radiology, for technical examinations and for guard-duty. Pharmaceutical costs cover the medication during hospitalisation. Extras are costs that cannot be placed in an other category and cover telephone costs, extra water bottles, television, and so on. The financial data of all, but one, patients were obtained.

Hospital stay ranged from 2 to 71 days. The median duration was 7 days; the mean $9,4 \pm 9,0$ days, with a mean total cost of 3093,19 euro. The total hospitalisation costs per patient ranged from 593,35 euro to 24142,37 euro; the total daily costs ranged from 96,63 euro to 663,68 euro, with a mean of 322,37 euro. Most of the costs were explained by the stay in the hospital; medical fees and pharmaceutical costs accounted for only 25% of costs. Of total costs, 88 % was covered by the public health insurance system and 12 % was covered by patient co-payment.

DISCUSSION

In this retrospective study we describe 107 cases of contact lens related corneal ulcers hospitalised over the past 7 years. As our cases included only patients hospitalised in the university centres, caution must be applied in the interpretation of these numbers. First, contact lens related corneal ulcerations managed on an outpatient basis are not included in our study, because there is no compulsory registration and relevant files are very difficult to trace.

Second, the survey was limited to the tertiary patient care level in the academic centres: at this level we could be sure to have all the information on a well defined group of patients in the course of the years studied.

We know that patients hospitalised for this pathology in other centres are missing as well as those managed on an outpatient basis, but we realised from the beginning that we would not be able to come up with incidence figures for infectious keratitis in the Belgian lens wearing population for the reasons mentioned above. We aimed to determine if there were any changes in the incidence of this pathology in the Belgian university hospitals in the last seven years. We clearly notice a rising trend in the number of hospitalisations: 5 admissions in 1997, steadily rising to 22 in 2001 and plateauing at that level in 2003 (Fig 1).

It is remarkable that 93,5 percent of all hospitalisations occur in 4 of the 8 university centres: Antwerpen, Gent, Leuven and Liège. The four university hospitals of Brussels admitted only 7 patients (6,5 %) with contact lens induced ulcerations in the period 1997 - 2003.

We checked if patients living in Brussels were treated at the other university hospitals: this is the case for 3 patients who were treated and hospitalised in the university hospital of Leuven and one in Liège. This finding of a markedly uneven distribution over the country of patients hospitalised for corneal ulceration could possibly be explained by a different policy of hospital admission. In Antwerp, Gent, Leuven and Liège the consensus is to hospitalise patients with central, sight-threatening lesions, especially when these seem to have a fulminant course. The patient is hospitalised so that intensive topical treatment can be given around the clock, day and night for the first 24 to 48 hours. In Brussels, it is judged that, in view of the shortage of hospital beds, the (younger) group of patients with contact lens related ulcerations, is more capable of self-administering eye drops and of being followed-up daily on an ambulatory basis than the (older) group of patients with ulcerations related to ocular surface disease.

Steady increase in contact lens wearers is noted in the past decade. In 1995, it was estimated that about 3,5 % (SOBEMAP 1995, unpublished data) of the Belgian population used contact lenses. A recent study by FADICON shows that the estimated number of contact lens wearers has increased to 6,5 % in 2003 (FADICON 2004, unpublished data). Ninety-three percent of the Belgian contact lens wearing population uses soft contact lenses: most popular are monthly renewal lenses (54%), followed by conventional soft lenses (12%) and daily disposables (11%). Continuous wear (2%) is not so widely represented in the Belgian population. Seven percent uses rigid gas-permeable lenses (Figure 3).

Taking into account the limitations of our study, one might nevertheless argue that the number of contact lens related corneal ulcerations has increased much more than could be expected from the increase in contact lens wearers. This trend (6) seems to have evolved despite the success of planned replacement lenses replacing conventional lenses, an important evolution in the nineties. One could argue that 107 cases, spread over 8 university hospitals in 7 years time is a relatively low figure, but the fact remains that these are almost all severe vision-threatening ulcerations. As described in the li-

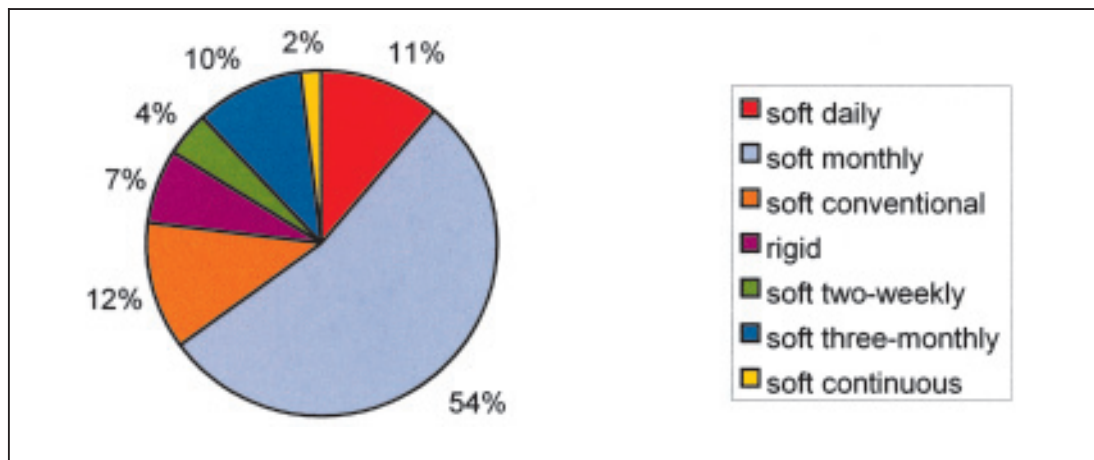


Fig 3. Type of contact lenses used in Belgium in % (from FADICON)

temperature (2,4,7,8,10,15), the majority of patients are younger than 40 years old and have no medical or ophthalmologic history, apart from their refractive errors. Nilsson and co-workers (7,8) found a surprisingly good visual acuity, due to the peripheral location of the lesions. We found that the visual outcome was much less favourable because of the central location of the ulceration: in 80 % of all affected eyes this resulted in a mean loss of visual acuity of 4 lines. Furthermore 16 eyes underwent penetrating keratoplasty and 1 eye with an Acanthamoebic infection was eviscerated, which shows the importance of this sight-threatening complication.

Unexpected was the fact that 3 patients with daily disposable lenses developed a serious corneal ulcer. Two of the 3 cultures showed *Pseudomonas aeruginosa*. Although infectious keratitis in daily disposable soft contact lens wear should be highly unlikely, it has been reported in the literature (1,3,16). With daily disposable lenses there is no need for lens cases nor for decontamination liquids; in theory the reservoir for bacterial contamination of the cornea is eliminated. A perfectly clean and sterile lens is put on the eye right out of its blister day by day, and still this is not sufficient to eradicate contact lens related keratitis. Probably the patient could be the weak link in not correctly using an optimally designed contact lens system. We questioned the patients on their lens care practices and compliance with the wear-

ing schedule: one patient admitted not following the guidelines and he wore the lenses for several days, even at night. The majority of the patients studied were careless while manipulating their lenses, though factors inherent to the patient, e.g. ocular surface disturbances such as tear film dysfunction, are very important regarding the pathogenesis of infectious keratitis. One might hypothesize that daily contact lenses as well as other lenses, disturb the physiology of the cornea, creating epithelial lesions and allowing bacteria to adhere and invade the stroma. Newer silicohydrogel materials with higher oxygen permeability, available as monthly and as two-weekly replacement lenses, might be the way forward for safer daily disposables.

In conclusion, our study confirms that the problem of contact lens related corneal ulcerations has not disappeared despite considerable technological advances in contact lens wear and lens care. The most known risk factors for ulceration are soft contact lenses, permanent wear and bad compliance with care regimens and wearing schedules. Permanent wear is not frequent in Belgium, because of bad experiences with this mode of contact lens wear in the past. Problems with compliance will always be an issue despite the strict safeguards we try to impose: the weak link remains the patient. Although our study is not fully representative for this health problem in Belgium, it surely demonstrates the increasing importance of in-

fectious complications caused by contact lenses and the costs generated to the Health Insurance Resources. We want to give a signal to the authorities that adaptation of contact lenses needs to be supervised by a specialist who can counsel the wearer on the best available option and who can encourage the patients' compliance through regular follow-up.

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