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CLINICAL RESEARCH

Industrially Prefabricated Cement Spacers: Do Vancomycin- and Gentamicin-impregnated Spacers Offer Any Advantage?

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Abstract

Background Industrially preformed antibiotic-loaded cement spacers are useful to facilitate the second stage of two-stage exchange arthroplasty for infected THAs and TKAs. However, whether gentamicin alone or a combination of antibiotics (such as vancomycin and gentamicin) is more effective is not known.

Questions/purposes We therefore sought to compare industrially prefabricated spacers containing either gentamicin or gentamicin and vancomycin with respect to (1) infection control, (2) complications, and (3) quality of life, pain, and patient satisfaction.

Methods We performed a review of 51 patients with chronic infections treated at one center using either gentamicin or vancomycin and gentamicin-prefabricated spacers. The former were used exclusively from January 2006 until May 2009, and the latter from June 2009 until July 2011, and there was no overlap. We collected data on demographics, immunologic status (McPherson classification), prosthetic joint infection location, type of prosthesis, microbiologic results, and time between stages. We evaluated the primary outcome of infection control or recurrence after at least 12 months followup. We also recorded complications. Each patient completed a quality-of-life survey, VAS, and a self-administered satisfaction scale.

Results The overall infection control rate was 83% after a mean followup of 35 months (range, 12.4–64.7 months). There were no differences between gentamicin and vancomycin and gentamicin spacers in terms of infection eradication (80 % versus 85 %, respectively; p = 0.73), nor in terms of complications, quality of life, pain, or satisfaction scores.

Conclusions Prefabricated, antibiotic-loaded cement spacers has been proven effective for infection control in TKAs and THAs but with the numbers available, we did not find any differences between a gentamicin or vancomycin and gentamicin-prefabricated spacer, and therefore, we are unable to validate the superiority of the combination of vancomycin and gentamicin over gentamicin alone. Because of the higher costs involved with vancomycin and gentamicin spacers, and the potential risks of unselective use of

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vancomycin, further comparative studies are necessary to evaluate their role in the treatment of infected THAs or TKAs.

Level of Evidence Level III, therapeutic study. See the Instructions for Authors for a complete description of levels of evidence.

Introduction

Infection is a devastating complication after a TKA or THA, with an incidence of 1% to 2%. [41]. To our knowledge, Wilde and Ruth [40] and Booth and Lotke [7] were the first to use an antibiotic-impregnated spacer block after first-stage débridement and reported infection control rates of 80% and 96%, respectively, with improved function. Subsequently, use of antibiotic-impregnated bone cement spacers during the first stage has been considered the standard of care for patients with a chronic infection at the site of a joint infection [10, 19]. There are numerous types of mobile prosthesis-like spacers available [14, 25, 27, 30, 36, 37], one of which is an industrially preformed antibiotic-loaded cement spacer [25, 27]. These spacers are preformed at the factory and loaded with a fixed type and amount of antibiotic.

The theoretical advantages of using a prefabricated system [27] are: (1) the implant has been proven mechanically safe; (2) pharmacologically, such devices have proven reliably effective (that is, they provide standardized antibiotic release); (3) the improved joint geometry they offer can provide better function and quality of life; and (4) their use can save operative time during the first-stage procedure. In the initial models, the chosen antibiotic was gentamicin [27] owing to its wide spectrum of activity and favorable properties of release from bone cement. With the emergence of gentamicin-resistant bacteria, the addition of two potentially synergistic antibiotics to bone cement has become attractive [5]. Vancomycin and gentamicin often are combined [2] for their potential synergistic effect [33] and improved elution [5] from bone cement. However, whether adding vancomycin to prefabricated antibiotic spacers results in improved infection eradication, less pain, or better function is unknown.

We therefore sought to compare industrially prefabricated mobile cement spacers containing either gentamicin or gentamicin and vancomycin, with respect to (1) infection control, (2) complications, and (3) quality of life, pain, and patient satisfaction.

Patients and Methods

We performed a review of all patients with a chronic THA or TKA infection treated at one center using either gentamicin or vancomycin and gentamicin prefabricated spacers. Our center is a 900-bed tertiary university hospital which houses a national-reference musculoskeletal infection unit. The study was conducted as part of the routine work of our institution. Institutional review board approval was not required because patients were treated according to local standards of care; all patients signed an informed consent.

Gentamicin spacers were used exclusively from January 2006 until May 2009, and vancomycin and gentamicin spacers were used from June 2009 until July 2011. There was no overlap. A total of 51 patients were treated during the study period, 10 of whom were lost to followup (six from the gentamicin group and four from the vancomycin and gentamicin group), leaving 41 patients available for the study. A total of 46 spacers had been used in these 41 patients. The minimum followup was 12 months (range, 12.4–64.7 months) and the patient group included 20 men and 21 women ranging in age from 34 to 84 years old.

Both spacer types were manufactured by the same supplier (Tecres, Verona, Italy). We collected data on demographics, immunologic status (McPherson classification) [22], location of joint infection, type of prosthesis, microbiologic results, time between stages, adverse events, and clinical outcomes. All patients were classified following the Tsukayama system, which classifies joint infections based on time from prosthesis implantation [34]. Patients were divided into two groups according to the type of spacer used: gentamicin spacers or vancomycin and gentamicin spacers. Twenty spacers were implanted in the group of patients with gentamicin spacers (43.47%) and 26 (56.53%) in the group with vancomycin and gentamicin spacers (Table 1).

Using the systemic host grade of the McPherson classification, 16 patients were categorized as Type A uncompromised (39%), 22 as Type B compromised (54%), and three as Type C significantly compromised (7%). Twenty-one patients sustained TKA infections (51.22%) and 20 had THA infections (48.78%). In all patients, the onset of infectious signs occurred at least 4 weeks after implantation; that is, a late chronic Type IV infection. In 27 cases (66%), the failed septic implant was a primary arthroplasty prosthesis, and in 14 cases (34%), it was revision prosthesis (Table 1).

The final diagnosis of infection was made when a patient met at least one of the following criteria, as recommended by the Infectious Disease Society of America [24]: (1) presence of chronic sinus; (2) presence of purulent fluid in the joint observed during surgery; (3) at least two positive cultures of the same bacteria from intraoperative tissue samples; and (4) positive intraoperative histologic evaluation.

Table 1. Demographic information

Demographic	Gentamicin	Vancomycin and gentamicin	p value
Sample size	20 spacers/19 patients	26 spacers/22 patients	
Age of patients (years) (95% CI)	68.21 (34.25–81.49)	64.46 (35.16–84.19)	0.388
Sex	9 male (47%)/10 female (53%)	11 males (50%)/11 females (50%)	1.000
BMI (kg/m^2) (95% CI)	29.92 (18–38)	29.26 (21–39)	0.574
McPherson Type A	6 (32%)	10 (45%)	0.491
McPherson Type B	12 (63%)	10 (45%)	
McPherson Type C	1 (5%)	2 (10%)	
Knee or hip	11 (57.89%)/8 (42.11%)	10 (45.45%)/12 (54.55%)	0.536
Primary or revision surgery	14 (73.68%)/5 (26.32%)	13 (59.09%)/9 (40.91%)	0.510
Time from first to second stage (95% CI)	97.39 days (34–235 days)	214.26 days (47–500 days)	0.010

Spacer Descriptions

The gentamicin knee spacer SpacerK® (Tecres) is preformed at the factory with an ultracongruent condylar knee prosthesis design (Fig. 1) using gentamicin-impregnated acrylic cement and produced in three sizes. The three sizes contain, respectively, 0.8 g, 1.1 g, and 1.8 g active gentamicin. The vancomycin and gentamicin knee spacer Vancogenx® (Tecres) is loaded with a 1:1 concentration of antibiotics, containing a combined total of 0.9 g, 1.3 g, and 1.9 g antibiotics, respectively.

The gentamicin hip spacer (SpacerG®) is preformed at the factory and resembles a femoral prosthesis (Fig. 2) made of gentamicin-impregnated acrylic cement. The inner part of the spacer consists of a stainless steel rod, which provides mechanical stability. These spacers are available in six versions: three head sizes (46, 54, and 60 mm), and in short-stem (153–168 mm) and long-stem (275–290 mm) versions. Depending on head size and stem length, the spacers contain from 1.2 g to 3.2 g active gentamicin.

The vancomycin and gentamicin hip spacer (Vancogenx®) is loaded with a 1:1 concentration of antibiotics containing a combined total of 1.1 g to 3.2 g antibiotics, respectively.

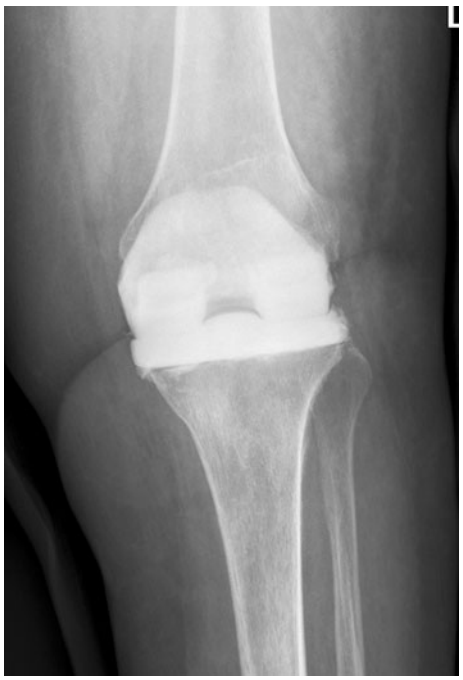

Fig. 1 The radiograph shows an industrially premade knee spacer used during the spacer stage of a two-stage revision TKA.

Operative Technique

The same two-stage protocol was used in all cases. In the first stage we performed thorough débridement. Before administration of antibiotics, at least six specimens were taken for culture. All surgical fields were thoroughly irrigated with a low-pressure system followed by implantation of a prefabricated antibiotic-loaded cement spacer. According to our protocol, the second-stage procedure is done only after a minimum of 12 weeks of oral systemic antibiotic treatment and when C-reactive protein and erythrocyte sedimentation rate levels have returned to normal. Patients were discharged home and outpatient followup was performed in the office. Patients were assessed for presence of complications related to the spacer, including dislocation, breakage, infection recurrence, spacer-related bone loss, and drug-related complications. At the second stage, intraoperative analysis of frozen sections was used routinely for identification of infection at the time of revision arthroplasty. Feldman's criterion was used, that is, at least five *polymorphonuclear leukocytes* in at least five high-power fields [4]. At least six tissue samples were collected at the time of the second-stage procedure [12]. All patients followed a similar antibiotic protocol after surgery under the guidance of an infectious diseases expert. In general, the antibiotic treatment was

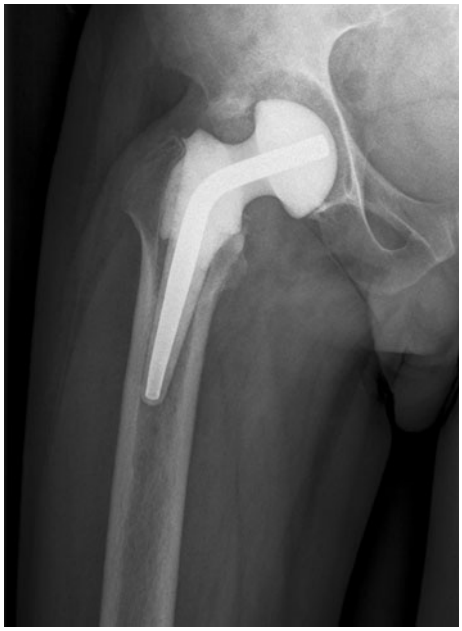

Fig. 2 The radiograph shows an industrially premade hip spacer used during the spacer stage of a two-stage revision THA.

selected according the susceptibility profile of the bacteria. If an oral antibiotic (with high bioavailability) was available, a 12-week-long treatment was selected; if not, a course of intravenous antibiotics for a minimum of 6 weeks was the preferred treatment. With staphylococci infections, a combined treatment including rifampicin is the preferred antibiotic combination; with gram-negative infections fluoroquinolones are the preferred antibiotic.

Intraoperative cultures at the time of the first-stage procedure were available for all study patients. The most common infecting organisms were coagulase-negative staphylococci (Table 2). Operative cultures were negative in five patients; however, each of these patients had definitive evidence of infection [24].

Followup Outpatient Protocol

After the second-stage surgery, all patients were evaluated at least once within the first 6 weeks and then at approximately 3 months, 6 months, 1 year, and yearly thereafter.

We defined treatment failure [9] as the need for subsequent infection-related surgery for persistence or relapse of the infection, the need for prolonged suppressive antibiotic treatment, or the presence of infection symptoms observed at the outpatient followup.

At the final outpatient visit, each patient was asked to fill out three questionnaires. Pain was assessed in all patients with a VAS, which uses a simple numerical score of 0 to 10 [18]. The assessment of health-related quality of life after the procedure was measured used the SF-12 Health Survey version 2 (SF12v2) [31]. Finally, patients responded to a short, self-administered satisfaction scale [20] regarding their personal satisfaction with the surgical procedure. Items are scored on a 4-point Likert scale. The scale score is the unweighted mean of the scores from the individual items, ranging from 25 to 100 per item (with 100 being the most satisfied).

Statistical Analysis

All the recorded data were entered into an Excel® database (Microsoft, Redmond, WA, USA) and SPSS (SPSS 20.0, Student Version for Windows; SPSS Inc, Chicago, IL, USA). Differences between quantitative variables in the groups studied were analyzed with Student's t-test for the comparison of means, and asymmetric samples were analyzed with the nonparametric Mann-Whitney U test. Comparison of medians was done with the nonparametric Gibbon test, and differences between qualitative variables were analyzed by the chi square test. A p value of 0.05 or less was considered statistically significant. A power analysis was performed with an alpha of 0.05 and the difference detected in our study.

Table 2. Microorganisms isolated during first-stage surgery

Single organism	Multiple organisms	Culture negative
Coagulase-negative *Staphylococcus aureus* (9 methicillin-resistant) 14	Coagulase-negative *Staphylococcus aureus* (sensitive) and *Corynebacterium* 1	5 (10.42%)s
Staphylococcus aureus (none methicillin-resistant) 4	*Staphylococcus hominis* and *Staphylococcus costellatus* 1	
Propionibacterium acnes 7	Coagulase-negative *Staphylococcus* (sensitive) and *Propionibacterium acnes* 1	
Pseudomonas stutzeri 1	*Escherichia coli* and *Proteus mirabilis* 2	
Escherichia coli 1	Coagulase-negative *Staphylococcus aureus* (resistant) + *Enterococcus faecium* 1	
Streptococcus pyogenes 1	*Propionibacterium acnes* + *Streptococcus viridans* 1	
Streptococcus agalactiae 1	*Streptococcus viridans* + *Staphylococcus capitis* 1	
Streptococcus oralis 1		
Morganella morganii 1		
Enterococcus faecalis 1		

Results

At final followup, there was no difference in the frequency of infection relapse between the two groups. In the gentamicin and vancomycin and gentamicin groups, at the end of followup after the two-stage replacement revision four of 20 (20%) and four of 26 (15.38%) patients experienced relapse, respectively (p = 0.73). We were unable to find any factors that were associated with an increased risk of infection recurrence (Table 1). Overall, relapse occurred in eight of the 46 patients with septic failed arthroplasties who had two-stage revisions using prefabricated articulating spacers, giving an overall infection control rate of 83%. All but three patients (all in the vancomycin and gentamicin spacers group) had reimplantation of prostheses. Two of these three patients who did not have a new prosthesis reimplanted had recurrence of infection with a discharging wound during the period without drugs. Both of these patients underwent another débridement with implantation of a new articulating spacer. At the time of the study, both were still awaiting the second-stage procedure. The other patient who did not have reimplantation of a new prosthesis was not considered suitable for reimplantation owing to her impaired medical status.

In three patients, two in the gentamicin group and one in the vancomycin and gentamicin group, it was necessary to repeat the first-stage surgery because of recurrence of infection before the infection could be considered controlled and the second-stage surgery could be scheduled (Table 3).

There were few complications associated with the spacers, and there were no differences between the groups in terms of complications. In the gentamicin group we observed two spacer dislocations; one involved a knee spacer and the other a hip spacer. In the vancomycin and gentamicin group, only one hip spacer dislocation was recorded. In the gentamicin group, one case of skin necrosis was observed in a patient with a knee spacer. No skin necrosis was observed in patients in the vancomycin and gentamicin group. No spacer breakage or reaction to the cement-on-cement articulation was recorded in either group, and no patients experienced drug-related complications.

There were no differences in quality of life, pain, or patient satisfaction between the two groups (Table 4).

Discussion

Infection is a devastating complication after TKA or THA. The two-stage exchange approach using an antibiotic-loaded cement spacer has become the preferred treatment for any chronically infected TKA or THA [10, 16, 19, 25, 27, 28, 36, 41]. The rationale for the choice of antibiotics to be included in such local delivery systems must follow several principles [10, 17], but the antimicrobial activity of the antibiotic at the infection site is of paramount importance, since drug selection depends on the microorganism(s) to be targeted. Because aminoglycosides meet all the requirements, they were considered the preferred antibiotics for this treatment approach [6, 10, 25, 27, 28, 41]. *Staphylococcus* species are the principal bacterial family related to TKA or THA infections [13, 23, 29], therefore a possible increase in aminoglycoside resistance in staphylococci causing an infection is a concern, and potentially might impact the utility of classic aminoglycoside-impregnated cement spacers [3, 5, 13, 29, 35]. This suggests that the use of other antibiotics or combinations of antibiotics in bone cement could be more effective for elimination of infection. The potential effectiveness of a combination of vancomycin and gentamicin in cement spacers has been suggested [5, 32, 33]. The vancomycin and gentamicin combination theoretically has a threefold advantage: (1) the potential synergy between vancomycin and gentamicin against gram-positive bacteria [17, 33, 39]; (2) the possibility of improved antibiotic elution from the spacer resulting from such a combination [5, 21, 26]; and (3) the possibility that such an antibiotic combination results in a decreased risk of bacterial growth on the surface of the cement spacer, that is, cement spacer colonization, which could be detrimental to curing the infection [1, 6]. However, to our knowledge, no comparative study has been published addressing this question. We therefore wanted to compare the efficacy of industrially prefabricated spacers containing either gentamicin or gentamicin and vancomycin, with respect to (1) infection control, (2) complications, and (3) quality of life, pain, and satisfaction. To our knowledge, there is no previously reported comparative study examining clinical outcomes using gentamicin and vancomycin and gentamicin industrially prefabricated cement spacers.

There were some limitations to our study. First, the study is a retrospective analysis with the inherent limitations of a retrospective design, specifically the inability to obtain all data that may be helpful. Second, our followup was limited to a minimum of 12 months because we have used these vancomycin and gentamicin spacers only in recent years. Future studies should include longitudinal followup of these patients. Third, there were numerous potential confounding factors, such as the use of varying antibiotic regimes and doses (even among the spacers used, owing to their different sizes), patient comorbidities, and the differences in interval between first and second surgeries among the groups. Fourth, the spacers were used unselectively, regardless of the susceptibility profile of the infecting bacteria. Finally, statistically significant results were not obtained and could be attributable to insufficient sample size and statistical power (Type II error; with the

Table 3. Operative variables

Patient number	Sex	Procedure	Type of surgery	McPherson host type	Isolated bacteria	Spacer type	Reimplantation surgery	Complications	Interval between the two stages (months)	Followup (months)	Infection control
1	M	TKA	Primary	A	*Pseudomonas stutzeri*	VG	Cemented hinge revision knee	Hematoma	6.03	18.50	Yes
2	F	TKA	Revision	A	*Propionibacterium acnes* + *Streptococcus viridans*	VG	Cemented hinge revision knee	None	8.30	24.77	Yes
3	F	TKA	Primary	A	*Staphylococcus capitis* + *Streptococcus viridans*	VG	Cemented hinge revision knee	None	3.40	20.20	Yes
4	M	TKA	Primary	B	*Propionibacterium acnes*	G	Uncemented revision knee	None	4.93	46.80	Yes
5	M	TKA	Primary	C	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	Cemented hinge revision knee	None	9.20	23.20	Yes
6	F	TKA	Primary	C	*Escherichia coli*	G	External fixation knee fusion	Skin necrosis	0.93	21.73	Yes
7	M	TKA	Primary	A	*Propionibacterium acnes*	G	Cemented hinge revision knee	None	2.83	22.57	Yes
8	M	TKA	Primary	B	Methicillin-sensitive coagulase-negative *Staphylococcus aureus*	G	Uncemented hinge revision knee	Hematoma	7.57	64.67	Yes
9	M	TKA	Primary	B	*Negative cultures*	G	Uncemented revision knee	None	1.30	58.80	Yes
10	F	TKA	Primary	B	*Negative cultures*	G	Uncemented hinge revision knee	None	5.00	59.77	Yes
11	F	TKA	Primary	A	Methicillin-sensitive *Staphylococcus aureus*	G	Uncemented hinge revision knee	Spacer dislocation	0.70	61.73	No
12	F	TKA	Revision	A	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	External fixation knee fusion	None	1.57	43.13	Yes
13	F	TKA	Primary	A	Methicillin-sensitive coagulase-negative *Staphylococcus aureus*	G	Uncemented revision knee	None	4.93	47.03	Yes
14	M	TKA	Primary	A	Methicillin-sensitive coagulase-negative *Staphylococcus aureus* + *Corynebacterium*	VG	Cemented hinge revision knee	None	3.83	39.00	Yes
15	F	TKA	Primary	A	*Propionibacterium acnes*	VG	Uncemented revision knee	None	4.30	31.20	Yes
16	F	TKA	Primary	A	*Propionibacterium acnes* + methicillin-sensitive coagulase-negative *Staphylococcus aureus*	VG	Uncemented revision knee	None	7.43	33.53	Yes
17	F	TKA	Primary	A	*Propionibacterium acnes*	G	Uncemented hinge revision knee	None	2.07	35.63	Yes

Table 3. continued

Patient number	Sex	Procedure	Type of surgery	McPherson host type	Isolated bacteria	Spacer type	Reimplantation surgery	Complications	Interval between the two stages (months)	Followup (months)	Infection control
18	F	TKA	Revision	B	*Staphylococcus hominis* + *Staphylococcus constellatus*	VG	Uncemented hinge revision knee	None	17.33	25.17	Yes
19	M	TKA	Primary	B	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	Uncemented hinge revision knee	Skin necrosis	18.90	23.47	Yes
20	M	TKA	Primary	A	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	G	Uncemented hinge revision knee	None	38.97	14.17	Yes
21	F	TKA	Primary	B	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	G	Cemented hinge revision knee	None	7.67	40.53	Yes
22	F	TKA	Revision	B	Methicillin-sensitive coagulase-negative *Staphylococcus aureus* + *Pseudomonas*	VG	Cemented hinge revision knee	None	0.80	25.33	Yes
23	M	THA	Revision	B	*Propionibacterium acnes*	VG	Uncemented revision hip	None	4.43	25.33	Yes
24	M	THA	Primary	A	*Streptococcus pyogenes*	VG	Uncemented revision hip	None	7.93	31.63	No
25	M	THA	Primary	A	Methicillin-sensitive coagulase-negative *Staphylococcus aureus*	VG	Uncemented revision hip	None	5.20	25.60	Yes
26	F	THA	Revision	B	*Negative cultures*	G	Uncemented revision hip	None	0.70	41.23	Yes
27	M	THA	Revision	B	*Streptococcus agalactie*	VG	Uncemented revision hip	None	3.57	20.70	Yes
28	F	THA	Revision	C	*Propionibacterium acnes*	VG	Total femur arthroplasty	Spacer dislocation	16.67	28.40	Yes
29	M	THA	Primary	B	Methicillin-sensitive *Staphylococcus aureus*	VG	Uncemented revision hip	None	3.73	30.03	Yes
30	M	THA	Primary	A	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	Uncemented revision hip	Peroneal palsy	16.00	32.80	Yes
31	M	THA	Primary	B	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	G	Uncemented revision hip	None	6.07	48.00	Yes
32	F	THA	Revision	A	*Negative cultures*	G	Uncemented revision hip	None	0.77	50.30	Yes
33	M	THA	Arthritis	B	*Propionibacterium acnes*	G	Uncemented revision hip	Spacer dislocation	1.90	28.60	Yes
34	F	THA	Revision	B	Methicillin-sensitive coagulase-negative *Staphylococcus aureus*	G	Uncemented revision hip	None	7.73	42.83	No
35	M	THA	Revision	B	Methicillin-sensitive *Staphylococcus aureus*	G	Uncemented revision hip	None	6.63	47.77	Yes

Table 3. continued

Patient number	Sex	Procedure	Type of surgery	McPherson host type	Isolated bacteria	Spacer type	Reimplantation surgery	Complications	Interval between the two stages (months)	Followup (months)	Infection control
36	M	THA	Revision	B	*Streptococcus oralis*	VG	Uncemented revision hip	None	10.97	32.23	No
37	M	THA	Revision	B	Methicillin-sensitive *Staphylococcus aureus*	VG	None	Repeated first stage	6.90	21.37	No
38	F	THA	Revision	B	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	Total femur arthroplasty	None	4.20	28.73	Yes
39	F	THA	Moore	B	*Escherichia coli* + *Proteus mirabilis*	G	None	Repeated first stage	1.87	45.87	No
40	F	THA	Moore	B	*Escherichia coli* + *Proteus mirabilis*	G	Uncemented revision hip	None	11.13	57.00	Yes
41	M	THA	Primary	A	*Negative cultures*	VG	Uncemented revision hip	None	5.77	30.60	Yes
42	F	THA	Revision	B	Methicillin-resistant coagulase-negative *Staphylococcus aureus*	VG	Uncemented revision hip	None	5.50	16.47	Yes
43	F	THA	Moore	B	Methicillin-sensitive *Staphylococcus aureus*	VG	None	Not second stage	0.00	25.17	Yes
44	M	THA	Primary	B	*Morganella morganii*	G	None	Repeated first stage	25.80	23.47	No
45	M	THA	Primary	B	Methicillin-resistant coagulase-negative *Staphylococcus* + *Enterococcus faecium*	VG	Uncemented revision hip	None	11.07	12.40	Yes
46	F	THA	Primary	A	*Enterococcus faecalis*	VG	None	Repeated first stage	10.47	14.17	No

G = gentamicin spacer; VG = vancomycin and gentamicin-spacer.

Table 4. Patient satisfaction, pain, and quality of life

Questionnaires	Gentamicin spacers	Vancomycin-gentamicin spacers	p value
SAPS (95% CI)	81.67 (25–100)	70.63 (25–100)	0.113
SF-12-PSC (95% CI)	29.75 (17.41–39.71)	31.75 (19.67–48.21)	0.722
SF-12-MSC (95% CI)	39.82 (15.35–18.46)	52.59 (28.85–68.95)	0.131
VAS (95% CI)	2.41 (0.00–8.00)	2.81 (0.00–8.00)	0.821

SAPS = Self-Administered Patient Satisfaction Scale; SF-12-PSC = SF-12 Physical Summary Component; SF-12-MSC = SF-12 Mental Summary Component.

differences observed in our study only a power of 6% was achieved requiring a sample size of 1080 per group to detect statistically significant differences which is a large sample size that is not realistic for this field). The selected definition of infection could be considered a limitation as well, although we have used a standardized and accepted definition according the Infectious Diseases Society of America [24].

Regarding the infection control rate, although the combination of gentamicin and vancomycin in the cement spacers makes some intuitive sense, we found no clinical or statistical difference in terms of infection control between use of prefabricated cement spacers impregnated with gentamicin and those with vancomycin and gentamicin. With the data available we are not able to validate the superiority of the combination of vancomycin and gentamicin over gentamicin alone. From a clinical point of view, no obvious difference in infection eradication rates has been observed where antibiotic cement spacers with different antibacterial loads and compositions have been used [15]. Although a high rate of gentamicin resistance in staphylococci causing chronic joint infections could be suspected, one may argue that aminoglycosides alone are still effective because of the high local concentration achieved with the local antibiotic treatment.

The overall control rate (83%) is comparable to rates reported in other studies [11, 25, 27, 38]. An ongoing criticism of the industrially premade spacer concerns the limited selection of antibiotics offered and the use of dosages less than those recommended for treatment of infections [16, 38]. The data from our study support the usefulness of prefabricated, antibiotic-loaded cement spacers for effective infection control of TKAs or THAs. Although the antibiotic dosages in such devices are inferior to those of handmade spacers, antibiotic elution may be superior [27, 32].

There were no differences between the gentamicin-only and vancomycin and gentamicin spacers in terms of complications in our patients. These prefabricated spacers have proven to be mechanically safe [11, 25, 27], with a low number of complications.

Infection after a TKA or THA reduces patient satisfaction and impairs functional health status and health-related quality of life [8]. Our patients expressed a high degree of satisfaction with the results of their treatment in septic revision cases. The overall satisfaction rate was 76%. We found differences between the two types of spacers. Similarly, in terms of pain and of quality of life as measured with the SF-12 v2, we found no difference between the two spacer types. To our knowledge, information regarding quality of life and patient satisfaction after the use of industrially prefabricated spacers has not been published.

We found no differences in terms of rate of infection control, complications, health-related quality of life, pain, or patient satisfaction between groups treated with either a gentamicin-only spacer or a vancomycin and gentamicin-impregnated spacer. With our data we are not able to validate the superiority of the combination of vancomycin and gentamicin over gentamicin alone, and because of the higher costs involved with vancomycin and gentamicin spacers and the potential risks of unselective use of vancomycin, further comparative studies are necessary to evaluate their role in the treatment of infected THAs or TKAs.

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