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ORIGINAL STUDY

Complications related to cement leakage in sacroplasty

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Data concerning the safety of sacroplasty in terms of cement leakage is scarce. Frequency, distribution patterns and clinical consequences of cement leakage were assessed in 33 patients (28 female, mean age : 74 ± 10 yrs ; bilateral SIF : n = 30, 63 sacroplasties) treated with sacroplasty between 06/2003 and 11/2010 in a retrospective study using patients' records, operative notes and postoperative radiographs. Cement leakage was noted within the fracture gap (27%), into veins (6%), neuroforamina (3%) or in the intervertebral disc space L5/S1 (2%). In one patient, cement leakage into the fracture gap led to unilateral radiculopathy of the 5th lumbar nerve root. Leakage into the fracture gap is at high risk of affecting the 5th lumbar nerve root due to the special course of its ventral branch over the sacral promontory. The risks of cement leakage with neurological impairment should be explained to patients.

Keywords : sacroplasty ; cement leakage ; sacral fracture ; complication.

INTRODUCTION

Sacral insufficiency fractures (SIF) related to osteoporosis with spontaneous sacral fractures were already described in 1982 (*22*). In general, the treatment of SIF is conservative with bed rest, analgesia and physical therapy. However, conservative management of SIFs may require up to one year for resolution of symptoms (*14,20*) and is associated with various complications related to immobilisation (*1,5,7,8,11*). As an alternative, percutaneous injection of polymethylmethacrylate (PMMA) into the fracture site (sacroplasty) for treatment of SIF was introduced in 2002 (*13*). Frey *et al* demonstrated an immediate reduction in the mean Visual Analogue Scale (VAS) pain scores with a concomitant reduction in analgesic requirements in a prospective study in 2008 (*12*). The efficiency of sacroplasty has been validated, but data on its safety in terms of intraoperative complications and occurrence of cement leakage is scarce. This report focused on the intraoperative complications and more specifically on the assessment of cement leakage rates, distribution patterns and clinical consequences after sacroplasty in particular.

PATIENTS AND METHODS

A consecutive series of 48 patients (41 female, mean age : 75 ± 11 yrs) was treated with fluoroscopically guided sacroplasty between June 2003 and November 2010

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at our institution. Sacral fractures were classified according to Denis (10) or Roy-Camille (24) classifications and the fracture description by Linstrom (21).

A retrospective study was conducted to analyze leakage rates in sacroplasty for the treatment of sacral insufficiency fractures. Patients with sacral fractures due to adequate trauma or tumour destruction, as well as cases with insufficient documentation were excluded from the study. According to these criteria, seven of 48 patients were excluded due to insufficient radiographic documentation, as well as a further five and three patients in whom sacral fractures were due to tumour destruction or trauma, respectively. In the remaining 33 patients (28 female, mean age : 74 ± 10 yrs), sacroplasty was performed for the treatment of sacral insufficiency fractures ; bilateral sacroplasty was performed in 30 cases. In these 33 patients, diagnosis and indication for sacroplasty was based on the sudden onset of low back and pelvic pain without trauma after a period of unsuccessful conservative treatment, and in general, on the use of plain radiographs and CT scans.

To describe cement leakage rates, distribution patterns and clinical consequences after sacroplasty, in general, the patients' records, operative notes, postoperative radiographic images and CT scans were analyzed. The potential patterns of leakage were classified as follows : intravenous leakage, cement extravasation into the fracture gap, into the neuroforamina, into the intervertebral disc space, into the sacroiliac joint and/or into the spinal canal. P-values are not provided as the statistical analysis used was descriptive.

METHODS

Patients with SIF were placed under general anaesthesia in the prone position on a radiolucent operating table allowing for fluoroscopic monitoring of cement application. Prophylactic antibiotic (Cefuroxime, Zinacef© 1.5 g, intravenous) was administered as a single shot dose before disinfection and sterile draping. In general, in cases with sacral fractures with displacement and wide fracture lines or in "U-type"-fractures in bilateral cases, additional iliosacral screws were applied to allow for cement injection after reducing the fracture gap or to enhance the strength of the fracture fixation device.

Fifteen patients were treated with sacroplasty alone. The S1 neuroforamina were identified in anteroposterior, inlet, outlet and lateral views. After stab incisions of the skin, 2.0 mm K-wires were guided under fluoroscopic control toward the midpoint between the lateral margin of the S1 foramen and the superomedial margin of the sacroiliac joint by the short-axis approach (13). Under lateral projection control the wires were adjusted to the appropriate depth, namely, into the center of the lateral mass. Bone marrow biopsy needles (8 gauge Jamshisdi biopsy needles, 4.2 mm outer diameter, 150 mm long ; Angiotech Medical Device Technologies, Gainesville, FL, USA) were guided over the K-wires, and the latter were then removed.

In eighteen patients, sacroplasty was supplemented with additional iliosacral screws. Prior to biopsy needle placement, iliosacral screws were placed percutaneously and fluoroscopically guided with respect to the landmarks for safe screw positioning (17).

Thereafter, as in vertebroplasty (15), for sacroplasty and/or augmentation of iliosacral screws the cement (Vertebroplastic©, DePuy, Acromed, Leeds, UK) was mixed to a paste-like consistency according to the manufacturers' instructions. Two ml standard syringes were filled with the material which was then injected by hand at room temperature under fluoroscopic control. To reduce the risk of cement leakage, initially, no more than 0.5 ml (for each needle) was applied and allowed to cure at body temperature for about 30-60 seconds (3). Then the filling of the sacral ala proceeded stepwise with only a short latency of the application of the cement within the cannula. As a result, the cement within the cannula cures faster at body temperature and has a higher viscosity. Cement application was controlled continuously from anteroposterior, inlet, outlet and lateral views using fluoroscopy. The flow of the cement should behave similarly to a "growing cloud" (15). Cement leaks anteriorly through nutritional vessels, posteriorly into the spinal canal, medially into the neuroforamina, laterally into the sacroiliac joint, cephalad into the intervertebral space or at least into the fracture gap were strictly avoided and filling was stopped when any cement extrusion was observed. As soon as the setting of the cement was completed, the needles were removed.

RESULTS

Data for the retrospective analysis of intraoperative complications and of cement leakage rates, distribution patterns and clinical consequences were available for all of the 33 patients. According to the fracture classification systems used, the majority of fracture lines were noted in Denis Zone 1 lateral to the neuroforamina (23 cases) ; in one patient, fracture lines were in Denis Zone 2. Nine further patients with bilateral

Table I. — Cement leakages after sacroplasty

Sacroplasty	no leakage	fracture gap	intravenous	neuroforamina	disc space L5/S1
unilateral (n = 3)	67% (2/3)	33% (1/3)	–	–	33% (1/3)
bilateral (n = 30)	43% unilateral (13/30) 47% bilateral (14/30)	40% unilateral (12/30) 7% bilateral (2/30)	13% unilateral (4/30)	0% unilateral (0/30) 3% bilateral (1/30)	– –
Σ (n = 63)	68% (43/63)	27% (17/63)	6% (4/63)	3% (2/63)	2% (1/63)

Leakages for unilateral, bilateral sacroplasties (in percent, amount of numbers in relation to total number) and for all performed procedures (Σ = overall leakages) and the distribution (intravenously, fracture gap, neuroforamina, disc space).

SIFs showed the "U-type" fracture pattern, with displacement into flexion in seven cases (Roy-Camille Type 1). Sacroplasty alone was performed in 15 patients, whereas in 18 patients additional iliosacral screws were applied due to wide fracture lines occurring as a result of displacement. Sacroplasty was performed bilaterally in 30 cases and unilaterally in three cases. In summary, the total number of procedures performed was 63. All surgeries were completed without any intraoperative complications except for cement leakages. In two-thirds (68%) of all sacroplasties, no cement leakage was noted. Cement leakages were mainly seen within the fracture gap in about 27% of cases, irrespective of whether iliosacral screws were placed (50% cement leakage) or not (40% cement leakage). Cement leakage into veins or into the neuroforamina was rarely observed (6% and 3%, respectively). Cement leakage into the disc space L5/S1 was seen in 2%, whereas leakage into the sacroiliac joint and/or into the spinal canal was not observed. The frequencies of cement leakages for unilateral, bilateral sacroplasty and for all performed procedures (overall leakages) as well as distributions of observed leakage sites after sacroplasty are shown in detail in Table I.

Cement leakage had no clinical significance except in one patient in which SIF was treated with unilateral sacroplasty and where cement leakage occurred anteriorly throughout the fracture gap as well as into the disc space L5/S1 – as seen in postoperative plain radiographs (Fig. 1). Initially, the patient reported pain relief subsequent to unilateral sacroplasty. However, three weeks postoperatively she requested an unscheduled outpatient consultation due to the sudden appearance of a radiculopathy of the 5th, left-sided lumbar nerve root without neurologic deficits. In the CT scans performed, hourglass-like compression of the left 5th lumbar nerve root was seen. The symptoms were reduced by the use of oral intake and local, paraforaminal injections of corticosteroids.

One patient required revision surgery for wound complications. After revision the wounds healed uneventfully. One patient died one year after surgery for reasons unrelated to surgery.

DISCUSSION

Sacroplasty has been shown to be a reasonable treatment option for SIF, providing early pain relief and recovery of agility and autonomy in daily living activities in the elderly (*12*). However, reports on potential complications with clinical significance related to sacroplasty are hardly found in the literature. As a result, an arbitrary reservation to the performance of sacroplasty might exist. In general, cannula malperforation with injury to the lumbosacral plexus, the A./V. iliaca interna and rami, the intervertebral disc and cement embolism are potential and serious complications. In the consecutive series of patients presented, no relevant intraoperative complications occurred irrespective of cement leakage, and all surgeries could be completed. In particular, cement leakage is of major concern (*27*) and this event might lead to significant clinical complications. In 2009, Bayley *et al* reviewed the published articles describing clinical results and complications related to sacroplasty (*2*). Cement leakages were described in five of fifteen

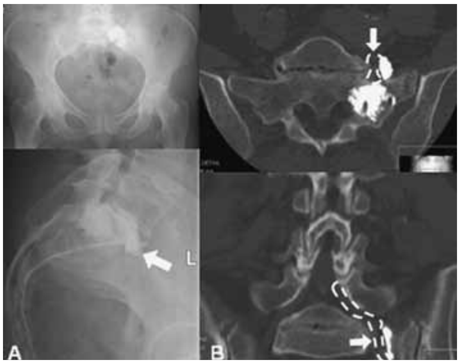

Fig. 1. — Sacral insufficiency fracture due to osteoporosis was treated with sacroplasty in a 64 year-old woman. Anterior cement leakage and cement leakage in the disc space L5-S1 were observed in (A) postoperative plain radiographs. Three weeks postoperatively the patient made an unscheduled visit to the outpatient service complaining of the sudden appearance of a radiculopathy of the 5th, left-sided lumbar nerve root without neurologic deficits. On (B) coronal and axial CT scans hour-glass-like compression of the left 5th lumbar nerve root was seen (white dashed line). The symptoms could be relieved by the use of oral intake and local, paraforaminal injections of corticosteroids.

reports, but they were without clinical significance in all patients. Cement leaked anteriorly in four of the four reported cases (*9,25*), posteriorly in one of three (*23*), into the S1 foramen in one of three (*16*), into the sacroiliac joint in one and intravenously in another out of four cases (*6*). In summary, only a small number of case reports or small case series indicating cement leakage after sacroplasty are available (*6,9,16,23,25*).

In the presented series of 33 patients (63 sacroplasties), no leakages were observed in the majority of cases. In cases where cement leakage did occur, these were mainly noticed within the fracture gap. Leakage into the fracture gap occurred independently of whether additional iliosacral screws were placed or not, indicating that additional iliosacral screws could not prevent cement leakage into the fracture gap from occurring. These leakages are at high risk of affecting the ventral branch of the 5th lumbar nerve root due to its special course over the promontorium of the sacrum. Since vertical sacral fractures are often located in this area, this nerve is – in contrast to other vertebrae – in close vicinity to cement leakage through the fracture gap. The latter pattern of cement leakage was seen only in one patient in a symptomatic extravasate with radiculopathy of the 5th lumbar nerve root, although this was without any neurologic deficits ; symptoms were recurrent under anti-inflammatory therapy. As a result, the function of the 5th lumbar nerve root needs to be assessed pre-operatively and the patient must be informed of the special vulnerability of this nerve.

In no cases was cement observed in the central canal or the sacroiliac joint. One patient was treated with bilateral sacroplasty, and cement leakage into both S1 neuroforamina was observed although this was without clinical consequences. In four patients with intravenous leakage, no clinical complications such as pulmonary embolism were noted in the patients' charts.

In summary, clinical consequences were hardly noticed even though cement leakage was frequently observed. Meticulous cement injection which takes into account the rheological and mechanical properties of the cement and the bone tissues might account for these results. The biomechanics of the cement injection are mainly influenced by the cement viscosity, whereas the risk of cement leakage is the lowest with high-viscosity cement (*3,4*). To increase the cement viscosity, the time elapsed after the commencement of mixing or the powder-to-liquid ratio might be increased. Such attempts are, however, unfavorable as the time period for cement application could be too short and a too high powder-to-liquid ratio might lead to cement inhomogeneities (*4*).

Furthermore, cement viscosity is not only a function of time but also of the environmental temperature as the polymerization rate of PMMA is temperature-dependent and the cement will cure faster at body temperature (*3*). Therefore, only a small and safe amount of cement is injected and will polymerize faster at body temperature. This highly viscous cement is supposed to fill sites of lowest resistance (e.g. fracture gap, venous drains) and might seal these areas during the second stage filling of the defect with cement of lower viscosity ("two stage injection technique") (*26*). In addition, the use of syringes with a small diameter enabled the surgeon to apply the required large injection pressures necessary for high-viscosity cement at the second stage of the procedure (*4*). In summary, cement with higher viscosity was applied in the present study and might account for the absence of expansive cement leakages with clinical significance.

The study is limited due to its retrospective design. However, in the latter patients, no clinical symptoms were reported during the postoperative course which could be related to cement leakages and we focused on the assessment of the safety of the procedure. As current literature with reports on the safety of sacroplasty is scarce and the number of sacral insufficiency fractures requiring treatment such as sacroplasty will increase with time (*18,19*), surgeons are reliant on further reports of complications of sacroplasty. As a result, the strength of the present report is the detailed description of cement leakages and presentation of clinical consequences in a larger series of performed procedures.

In summary, to prevent the occurrence of expansive or compressive cement leakages, the surgeon should be aware of the physical properties of the cement used. In addition, the surgeon should have an understanding of the tissue characteristics of osteopenic bone, since "bone permeability" in bone with an increased matrix porosity and/or increased pore sizes is raised, resulting in a decreased tendency of leakage (*4*). Moreover, potential variations between patients should be anticipated.

CONCLUSION

Due to the limited access and difficult intraoperative radiological imaging, the control of cement distribution remains difficult in sacroplasty. Cement leakages are frequently observed in sacroplasty, mainly into the fracture gap. Symptomatic cement leakages are rarely noted. Special attention should be given to the application of the cement with high viscosity. The risks of cement leakage with neurological impairment, especially of the 5th lumbar nerve root, should be explained to patients undergoing this procedure.

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