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Original article

Can the Reamer/Irrigator/Aspirator System replace anterior iliac crest grafting when treating long bone nonunion?

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ABSTRACT

Introduction: Autologous bone graft is the gold standard for filling bone defects associated with diaphyseal nonunions. It is typically harvested from the anterior iliac crest (AIC) despite the high complication rate. The Reamer/Irrigator/Aspirator System (RIA) was developed to recover the reaming aspirate and use it as autograft. Initially described for harvesting bone from the femur, the bone volume available is similar to the AIC site; however, its use directly at nonunion sites has been studied very little.
Hypotheses: Compared to AIC harvesting, RIA at a non-union site will result in (1) sufficient bone volume, (2) similar time to union and union rate, (3) lower morbidity.
Results: Two groups of patients received an autograft for aseptic nonunion of the tibia or femur for a bone defect up to 2 cm: the RIA group ($n = 30$) was followed prospectively and received an autograft by RIA while the AIC group ($n = 29$) was reviewed retrospectively and received an autograft by AIC. We compared the time to union and union rate, operative time, intake of analgesics, duration of hospital stay and complication rate between groups. The RIA provided sufficient bone, 60 cm^3 on average in a reliable manner. The union rate was similar between groups: 90% (RIA) and 89.7% (CIA) ($p = 0.965$), while the time to union was shorter in the RIA group (8.63 ± 1.47months vs. 10.08 ± 1.7 months) ($p = 0.006$). The operative time ($p < 0.0001$), analgesic intake ($p = 0.013$), length of stay ($p < 0.0001$) and immediate complication rate ($p = 0.0195$) were higher in the AIC group.
Discussion: For the treatment of aseptic long bone nonunion, autograft harvested by the RIA from the nonunion site results in similar union rate and time to union as AIC grafts without additional complications.
Level of evidence: IV, comparative retrospective study.

1. Introduction

Diaphyseal nonunion is a well-known complication of long bone fractures, with a prevalence of 2.5% to 46% depending on the location and severity of the bone, skin and vascular lesions [1,2]. For aseptic diaphyseal nonunions less than 2 cm, the addition of bone without site preparation is sufficient to achieve union [3]. Filling of a defect by an autologous bone graft remains the gold standard. The most common site for harvesting is the anterior iliac crest (AIC) because of its easy access and the large amount of bone that can be recovered [4]; however, this procedure is plagued by minor (9%–39%) and major complications (0.76%–25%) [5,6].

The medullary canal of long bones is another potential autograft harvest site [7]. The Reamer/Irrigator/Aspirator System™ (RIA) (DePuy Synthes Inc., West Chester, PA) is a reaming system coupled with irrigation and aspiration that was developed to reduce the intramedullary pressure, heat production, surgical time and fat embolism risk during reaming [8,9]. The system also makes it possible to recover the bone debris and reaming aspirate to use as a bone graft [10,11], with the latter being high in growth factors (FGFa, PDGF, IGF-I, TGF-b1) and BMP-2 [8,11–14]. One of the advantages of the RIA is that the bone harvesting is minimally invasive and has low morbidity. Several studies have documented the absence of additional morbidity when using the RIA [15–17] and two of them have reported identical union rates for the two techniques [15,17]. The aims of our study were to compare the two sources of autograft (AIC and RIA reaming aspirate from nonunion site) for treating tibial or femoral nonunions. We had three hypotheses:

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- RIA at a non-union site will recover sufficient bone volume to act as a graft;
- the union rate is identical whether the bone defect is filled with RIA aspirate or AIC;
- the morbidity of RIA is lower than AIC.

2. Materials and Methods

2.1. Study overview

This was a single-center, multisurgeon, continuous, comparative study. The inclusion criteria were:

- presence of a diaphyseal nonunion in the middle third of the tibia or femur defined as a lack of bone union 6 months after the trauma (no continuity on X-rays or no clinical and radiological improvement for at least 3 months);
- presence of a bone defect less than 2 cm.

The exclusion criteria were septic nonunion, nonunion without bone defect, defects larger than 2 cm estimated preoperatively on radiographs or intraoperatively, fracture fixation other than locked intramedullary (IM) nailing, dynamic IM nailing, intraoperative use of BMP, patients who received radiation therapy, chemotherapy, immunosuppressants or long-term corticosteroid therapy, pathological fractures, patients less than 17 years of age, incomplete medical records or less than 1 year follow-up.

Two groups of patients were established. The RIA group, in which patients operated between November 2008 and August 2010 for an aseptic diaphyseal nonunion of the tibia or femur with autograft taken from reaming aspirate at the nonunion site using RIA and locked IM nailing were enrolled consecutively and prospectively. Samples were collected from all patients intraoperatively without antimicrobial prophylaxis to confirm retrospectively that the nonunion was aseptic. During this period, all the patients with nonunion and a defect less than 2 cm were treated with this type of graft. The AIC (control) group consisted of all patients operated between January 2004 and November 2008 for aseptic diaphyseal nonunion of the tibia or femur with autograft from the AIC and locked IM nailing. They were reviewed retrospectively.

2.2. Surgical technique

The nonunion treatment method consisted of decortication and repermeabilization of the medullary canal. Static locked IM nailing was done after classic reaming to a diameter 1–1.5 mm greater than the nail diameter. The graft was then positioned at the nonunion site.

For the RIA group, planning of the reaming diameter was done by measuring the diameter of the medullary canal at the isthmus using fluoroscopy. The minimum reaming diameter with the RIA was 12 mm. The RIA was used only at the nonunion site. At the tibia, fibula osteotomy was done when it was not fractured.

For the AIC harvesting, a skin incision was made 1 cm below the iliac crest and 1.5 cm behind the anterosuperior iliac crest to ensure the lateral femoral cutaneous nerve was not damaged and the anterosuperior iliac crest was not weakened. The graft was harvested from the endopelvic face. The harvest was bicortical corticocancellous or pure cancellous, depending on the nature of the bone defect.

The rehabilitation protocol was the same for both groups: weight bearing was allowed starting at the 6th week postoperative and full weight bearing at 3 to 6 months. Passive mobilization of the knee and hip was done freely.

2.3. Data collection

The data were analyzed by an independent observer during postoperative visits at 45 days, 3, 6, 12 and 24 months and at the review visit. The reliability of the surgical technique was determined as the possibility of filling the bone defect, amount of bone graft collected (in cm^3), duration of the surgery, time to union and union rate (a fracture was considered healed when the patient no longer had pain at the nonunion site or during walking, and a callus bridging the fracture was visible on at least three of the four cortices on two orthogonal X-ray views). The morbidity was evaluated through the intraoperative and postoperative complication rate, the intake of level 3 analgesics, need for blood transfusion, duration of hospital stay, return to work at the previous level, and the Lower Limb Core Scale [18].

2.4. Statistical analysis

The statistical analysis was performed by our medical informatics department using SPSS V17 software (IBM, Armonk, New York). The population characteristics were described by their absolute values and percentages for the qualitative variables, and the mean ± standard deviation for the quantitative variables. The functional outcomes were summarized by the mean ± standard deviation for each score. The Chi^2 and Fisher test were used to compare percentages and the Mann–Whitney test was used to compare averages (number < 30). The significance level was set at alpha = 0.05.

3. Results

Fifty-nine patients were included in the study, 30 in the RIA group and 29 in the AIC group. There were 29 cases of tibial nonunion and 30 cases of femoral nonunion. The two groups were statistically similar (Table 1). The mean follow-up was 32 ± 7 months (25–41) with the same mean value for the two groups.

One of the main findings of this study was that the bone volume collected by the RIA in the fractured bone was sufficient, averaging 60 ± 23 cm^3 (30–75 cm^3). It was 51 ± 8 cm^3 in the tibia and 68 ± 6 cm^3 in the femur ($p = 0.251$) (Fig. 1). The duration of the surgery was significantly less in the RIA group; the union rate was comparable and the mean time to union was shorter in the RIA group (Table 2). Having an open fracture did not significantly impact the outcomes in the two groups.

There were no intraoperative complications in either group. One minor postoperative complication occurred in the RIA group (3%): hematoma over the greater trochanter that resolved spontaneously and did not require treatment. There were four immediate postoperative complications in the AIC group (14%): one hematoma over the AIC that resolved spontaneously with drain application; two cases of a cutaneous sensory deficit in the region of the lateral femoral cutaneous nerve (one lasting 2 months and one permanent); one case of an early infection requiring surgical lavage. The intake of level 3 analgesics and the mean length of hospital stay were significantly less in the RIA group. At the final review, the same proportion of patients had returned to work in both groups (RIA: 80% and CIA: 75.9%; $p = 0.701$). Ten of the 29 patients in the AIC group (34.5%) complained of pain at the harvest site.

4. Discussion

The primary aim of this study was to ensure that sufficient autologous bone graft could be harvested from the nonunion site by the

Table 1
Characteristics of the study population.

	RIA ($n = 30$)	AIC ($n = 29$)	p-value
Age (years)	38.9 ± 15.2	35.3 ± 14	0.430
Male (%)	21 (70%)	23 (79.3%)	0.412
BMI (kg/m^2)	23.9 ± 1.96	24.3 ± 3.17	0.958
Diabetes (%)	0 (0%)	0 (0%)	0.99
NSAIDs (%)	0 (0%)	0 (0%)	0.99
Smoker (%)	10 (30%)	11 (37.9%)	0.520
Femur (%)	16 (53.3%)	14 (48.3%)	0.702
Tibia (%)	14 (46.7%)	15 (51.7%)	0.698
Open fracture (%)	8 (26.7%)	10 (34.5%)	0.51
Previous surgical treatment with autograft	3 (10%)	1 (3.4%)	0.612
Time to surgical treatment of nonunion (months)	10 ± 5.1	8.7 ± 4.6	0.232
Mean bone defect size (cm)	1.2 ± 0.7	1.3 ± 0.6	0.341

RIA: Reamer-Irrigator-Aspirator system (DePuy Synthes Inc., West Chester, PA); AIC: anterior iliac crest; BMI: body mass index; NSAIDs: non-steroidal anti-inflammatory drugs.

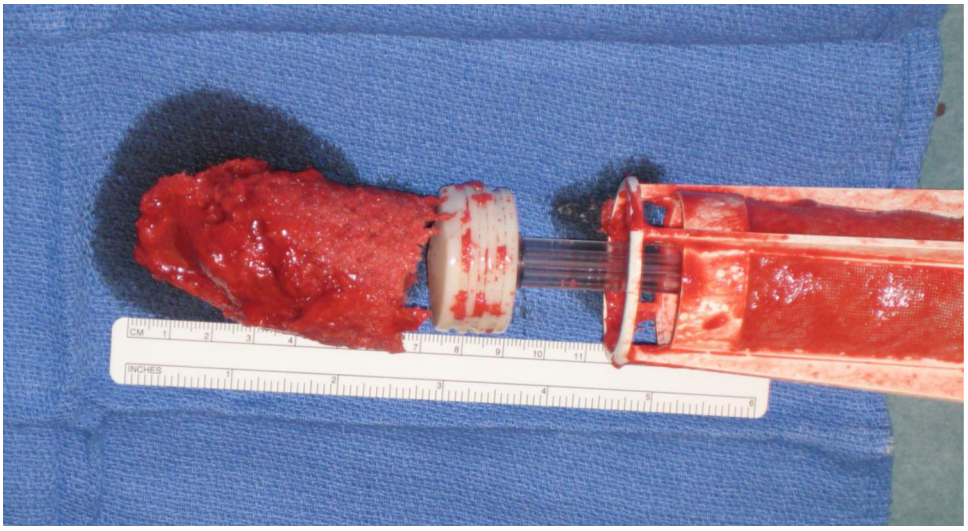

Fig. 1. Bone volume obtained with RIA.

Table 2
Results.

	RIA ($n = 30$)	AIC ($n = 29$)	p-value
Operative time (min)	134 ± 38	194 ± 33	< 0.0001
Transfusions (%)	3 (10%)	8 (27.6%)	0.083
Patients requiring level 3 analgesics (%)	8 (26.7%)	17 (58.6%)	0.013
Length of hospital stay (days)	7.4 ± 1.8	9.5 ± 1.9	< 0.0001
Union rate (%)	$n = 27$ (90%)	$n = 26$ (89.7%)	0.965
Time to union (months)	8.3 ± 1.5	10.1 ± 1.7	0.006
Return to work (%)	$n = 24$ (80%)	$n = 22$ (75.9%)	0.701
Lower Limb Core Scale (LLCS) Standardized Mean at completion	88.8 ± 7.9	91.7 ± 8	0.144
PCS at completion	48.9 ± 6.4	49.1 ± 7.7	0.496
MCS at completion	57.2 ± 8.3	54 ± 8.4	0.100
Immediate intraoperative and postoperative complications (%)	1 (3.3%)	4 (13.8%)	0.0195
Unlocking of nail	7 (29.2%)	6 (27.3%)	0.122
Follow-up	22.1 ± 6.2	56.7 ± 30.6	< 0.0001

PCS: Physical Component Score; MCS: Mental Component Score.

RIA. Although "sufficient" is highly subjective, it means that we did not have to harvest bone from other sites to fill bone defects up to 2 cm. Our results are consistent with those of other published studies [15,19,20] and with those when AIC graft is used [21,22]. In these cases, adding bone graft without preparing the site is sufficient to achieve union [3], which is confirmed by our study. Although the RIA was initially described for use in non-fractured femurs to obtain the largest amount of graft material, it is indicated for defects larger than 2 cm [23]. In our study, the amount of bone graft obtained at the nonunion site by the RIA is less than when used in a healthy femur, but still enough for the simple defects (< 2 cm).

Use of the RIA did not prolong the operative time since it is done during the reaming step needed to implant an IM nail. On average,

the procedure in the AIC group took 60 min longer. There is little information about this additional time in the literature. Kessler et al. [24] reported that harvesting from the AIC required an additional 35 min and harvesting from the posterior iliac crest required an additional 60 min (20 min of which was for patient repositioning).

The second aim of our study was to compare the union rate of the two techniques. The union rate was equal in the two groups and comparable to published studies reporting about 90% for RIA [15,19] and 80% to 96% for AIC harvesting [25,26].

The last aim was the compare the morbidity of the two techniques. Like in the Newman [19] study, there were no serious complications in the RIA group or any complications requiring additional treatment or changes in the rehabilitation protocol. We observed only one case of postoperative hematoma (3.3%) that resolved spontaneously. We hypothesize that using the RIA as the reaming method at the nonunion site before IM nailing instead of on a separate site does not alter the complications or postoperative course.

The intake of level 3 analgesics and the length of hospital stay were significantly greater in the AIC group. Our study was comparable to that of Belthur [15] who found that pain levels on a visual analog scale were higher in the AIC group, even at more than 3 months after the procedure. As for the length of hospital stay, we hypothesize that pain and more frequent recourse to level 3 analgesics led to these patients being monitored for a longer period of time.

In our study, 34.5% of patients had chronic pain (persistent pain at the final review). Our findings are consistent with other published studies reporting chronic pain rates between 26% and 38% [27,28], but higher than those found in an observational study of 92 patients [29].

Our study has several limitations. The data collection in the AIC group was retrospective. The mean follow-up was short in the RIA group and the sample sizes were limited. An important limitation relates to the technique used, which combines decortication, reaming and grafting, which makes it difficult to determine the contribution of the graft itself relative to the decortication and reaming; however the same techniques were used for both groups. Lastly, the lack of significant difference in the number of complications is likely related to the small sample size. Nevertheless, our study has several strong points. To our knowledge, this is an original study comparing use of RIA at the nonunion site with that of AIC grafting.

5. Conclusion

Recovering reaming aspirate from the nonunion site and using it as autograft in the context of aseptic diaphyseal nonunions up to 2 cm defect led to similar results to using AIC in terms of the union rate and time to union. While these results are encouraging, they must be confirmed in a comparative randomized study with larger defects.

Disclosure of interest

M.L.B., J.P.V. and R.V. declare that they have no competing interest.

P.M.: Newclip (consultant).

X.F.: Zimmer, Stryker (consultant).

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Author contributions

M.L.B.: writing of manuscript.

J.P.V.: data collection.

P.M.: data collection, reviewing of manuscript.

R.V.: data collection, reviewing of manuscript.

X.F.: writing of manuscript, review of manuscript.

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