Reamer Irrigator Aspirator versus Autogenous Iliac Crest Bone Graft for the Treatment of Nonunions: A Multi-Center Randomized Controlled Trial

Aaron Nauth, Jeremy Hall[1], Michael D McKee[2], Matthew Raleigh[3], Milena Vicente[4], Jennifer Hidy, Emil H Schemitsch[5], Cots Canadian Orthopaedic Trauma Society[6]
[1]St. MichaelS Hospital, [2]Banner - University Medical Center Phoenix, [3]Division of Orthopedic Surgery, Department of Surg, [4]St. Michael's Hospital, [5]University of Western Ontario, [6]COTS

INTRODUCTION:

The traditional gold standard for management of nonunions and bone defects is Autogenous Iliac Crest Bone Grafting (AICBG). Recently however, significant interest in the use of Reamer Irrigator Aspirator (RIA) for bone graft harvesting from the intramedullary canal has developed due to the potential for decreased pain, lower rates of harvest site complications, larger graft volumes, and biologic superiority. Despite such proposed advantages, prospective comparisons between RIA and AICBG are limited. Accordingly, we performed a multi-center (7 level 1 trauma centers), randomized control trial of AICBG vs. RIA bone graft for the treatment of long bone nonunions. We hypothesized that RIA bone graft would demonstrate a clinically significant reduction in postoperative pain and harvest site complications, with equivalent union rates to AICBG.

METHODS:

Patients aged 18-65 with a long bone nonunion or bone defect requiring bone grafting were eligible for inclusion. Nonunions were defined by 6 months duration of a nonunited fracture with no evidence of progressive healing over the previous 3 months. Bone defects were defined by the presence of a bone defect that, in the opinion of the treating surgeon, would not go on to heal without further intervention. Enrolled patients were randomized to either RIA bone graft or AICBG groups for the treatment of their nonunion and were followed to 1 year postoperatively.

Bone grafts were obtained in a standardized fashion in both groups. In the RIA group, bone graft was obtained from the femoral intramedullary canal via an antegrade or retrograde technique. In the AICBG group, graft was obtained via the anterior iliac crest. All patients received identical local anesthesia intraoperatively to the graft site following the procedure.

The primary outcome was visual analog score (VAS) for pain at the harvest site at 1 day postoperatively. Secondary outcomes were rates of union, complications, and reoperation, as well as functional outcomes and graft volumes obtained. VAS was recorded at 2 hours, 1 day, 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively. Radiographic assessment for union was completed at 6 weeks, 3 months, 6 months, and 1 year using a four-point scale (1-union, 2-moderate bone formation, 3-minimal bone formation, 4-no evidence of bone formation). Functional outcomes were assessed at baseline, 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively using the Short Musculoskeletal Function Assessment (SMFA) and Short Form-36 (SF-36).

Data is presented as mean ± standard deviation, 95% confidence interval, median and interquartile range, or percentage as appropriate. Differences between continuous outcomes were assessed using two-tailed t-tests or Mann-Whitney U tests for non-parametric data. Differences for categorical variables were assessed by Fisher's exact tests or Fisher-Freeman-Halton exact tests if contingencies were > 2x2. Repeated measures analysis of variance was used to compare the effect of treatment over time. A p value < 0.05 was considered statistically significant.

RESULTS:

Ninety-three patients were randomized (44 to RIA and 49 to AICBG) over 9 years. No baseline differences were detected between groups. Two patients (both from RIA group) did not complete the study, 1 withdrawing immediately following surgery and the other dying before the 3-month follow up. The primary outcome of VAS for harvest site pain was significantly lower in the RIA group at 1 day postoperatively (RIA=4.0±2.5, AICBG=5.5±2.7, p=0.02), but equivalent with AICBG at all other time points (see Figure 1). No differences were found in rates of complete union at 1 year (RIA=76%, AICBG=63%, p=0.55), nonunion complication rate (RIA=17%, AICBG=14%, p=0.78), overall complication rate (RIA=33%, AICBG=34%, p=0.66), or reoperation rate (RIA=26%, AICBG=22%, p=0.81). There was also no difference between the two groups in functional outcomes as measured by SMFA Function and Bothersome or SF-36 Physical and Mental components (see Table 1). Graft harvest site complications were minor and rare in both groups (RIA=4.7%, AICBG=4.1%, p=1.0). Significantly greater graft volume was obtained with RIA compared to AICBG (RIA=37.8±21.1 ml, AICBG=19.3±10.3 ml, p<0.001).

DISCUSSION AND CONCLUSION:

In this randomized trial we found that compared with AICBG, RIA bone graft significantly reduces early harvest site pain and provides significantly greater volumes of bone graft when used for the treatment of long bone nonunions. The rates of union, reoperation, and complications were similar between the two groups. We also found no difference in functional outcomes between the two groups. Both graft options result in a high rate of union with low rates of harvest site complications for the treatment of nonunions and bone defects. RIA bone graft may provide benefits over AICBG when large volumes of graft are required or a reduction in early graft harvest site pain is a priority.

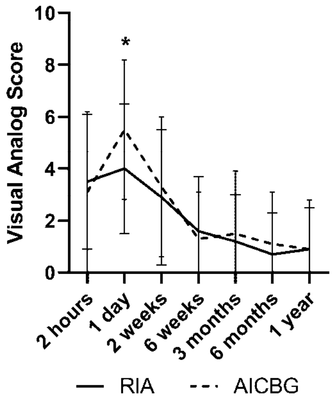

Figure 1: Harvest Site Pain VAS Scores Over Time
Data presented as mean ± standard deviation, * denotes $p < 0.05$.

Table 1: Comparison of Patient-Reported Outcome Measures

	RIA (n=44)	AICBG (n=49)	P value
SMFA Function			
Baseline	39.1±14.2 (34.8, 43.4)	36.9±17.9 (31.7, 42.0)	0.78
2 weeks	47.2±14.1 (42.7, 51.8)	48.5±16.0 (43.9, 53.1)	
6 weeks	40.5±15.1 (35.6, 45.3)	38.4±20.0 (32.6, 44.2)	
3 months	33.1±15.9 (27.9, 38.2)	34.7±21.1 (28.7, 40.8)	
6 months	29.1±16.3 (23.8, 34.3)	32.0±20.1 (25.9, 38.1)	
1 year	28.0±16.4 (22.7, 33.3)	28.4±20.1 (22.2, 34.6)	
SMFA Bothersome			
Baseline	45.2±21.9 (38.5, 52.0)	44.5±23.8 (37.6, 51.5)	0.92
2 weeks	47.4±24.7 (39.5, 55.3)	49.2±24.6 (42.0, 56.5)	
6 weeks	44.7±22.0 (37.7, 51.8)	42.3±26.5 (34.5, 50.1)	
3 months	37.9±22.8 (30.5, 45.3)	40.5±27.7 (32.5, 48.5)	
6 months	35.6±24.3 (27.7, 43.5)	36.6±27.3 (28.3, 44.9)	
1 year	37.3±24.8 (29.3, 45.3)	32.4±24.3 (24.9, 39.9)	
SF-36 PCS			
Baseline	33.4±7.4 (31.1, 35.6)	34.0±8.6 (31.5, 36.5)	0.63
2 weeks	32.9±8.9 (30.0, 35.8)	32.5±6.8 (30.5, 34.4)	
6 weeks	36.0±7.0 (33.7, 38.2)	37.6±9.1 (35.0, 40.2)	
3 months	38.4±8.8 (35.5, 41.2)	39.4±9.6 (36.6, 42.1)	
6 months	39.5±8.2 (36.9, 42.1)	40.6±9.7 (37.6, 43.5)	
1 year	41.1±10.0 (37.9, 44.4)	42.9±9.9 (39.9, 46.0)	
SF-36 MCS			
Baseline	48.6±12.1 (44.9, 52.3)	47.5±11.1 (44.3, 50.7)	0.4
2 weeks	47.0±12.2 (43.0, 50.9)	44.3±12.1 (40.9, 47.8)	
6 weeks	46.0±9.5 (42.9, 49.0)	45.0±11.5 (41.7, 48.4)	
3 months	47.1±12.3 (43.1, 51.1)	45.3±12.4 (41.7, 48.8)	
6 months	48.3±11.1 (44.7, 51.9)	46.0±11.6 (42.5, 49.5)	
1 year	46.2±10.9 (42.7, 49.8)	47.3±10.5 (44.1, 50.5)	

mean ± standard deviation (95% confidence intervals)