

Randomized Clinical Trial of Low Dose Single Antibiotic Loaded Cement versus High Dose Dual Antibiotic Loaded Cement in Patients Receiving a Hip Hemiarthroplasty after Fracture

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INTRODUCTION:

Hip fracture in older people is a global problem which significantly impacts health-related quality of life and places a huge socioeconomic burden upon healthcare systems. Surgical site infection (SSI) rates in patients receiving a hemiarthroplasty are a significant complication resulting in one-year mortality rate up to 50%. There remains controversy over the use of antibiotic loaded bone cement in hip fractures treated with hemiarthroplasty.

This trial compared the rate of deep surgical site infection in patients receiving high dose dual antibiotic loaded cement versus standard care low dose single antibiotic loaded cement.

METHODS:

We conducted a pragmatic multicenter, multisurgeon, randomized controlled trial of 4,936 people 60 years or over with an intracapsular hip fracture. Participants from 26 centers undergoing cemented hemiarthroplasty were assigned in a 1:1 ratio to either a low dose single antibiotic loaded cement (n=2,453) or high dose dual antibiotic loaded cement (n=2,483).

Outcome data were obtained through telephone interview with the participant, or the main caregiver where the participant lacked capacity, and from routine medical records including reoperation records, antibiotic details, microbiology reports, and imaging reports in relation to suspected infection.

The primary end point was deep SSI as defined by the Centers for Disease Control and Prevention definition of a “deep surgical site infection,” that occurs within 90 days of surgery. Secondary outcomes were quality of life at 4-months, complications including mortality, the rate of antibiotic prescription for wound healing complications other than deep SSI in the first 90 days, and resistance patterns for any wound infection.

RESULTS:

Primary analysis showed that the difference in the rate of deep surgical site infection was not statistically significant; low dose single antibiotic loaded cement 38 (1.7%) vs. high dose dual antibiotic loaded cement 27 (1.2%); odds ratio 1.43; 95% confidence interval (0.87-2.35); p-value 0.16. There was no difference in quality of life at 4 month (EQ-5D utility scores 0.39 single antibiotic vs. 0.40 high dose dual antibiotic cement; adjusted difference -0.008; 95% confidence interval (CI) -0.024-0.008; p=0.33). The odds ratio for mortality at 4-months was 1.06 (95%CI, 0.92-1.23), and was 0.97 (95% CI, 0.87-1.10) for other complications at any time.

There was no statistical difference in the number of participants given antibiotic prescriptions for wound healing complications other than deep surgical site infection. There were 45 participant (2.1%) prescribed antibiotics by 4 months in the low dose single antibiotic arm, and 37 (1.7%) in the high dose dual antibiotic arm with an odds ratio of 1.23 between treatment groups (95%CI 0.79, 1.91). There were also no differences in resistance patterns between treatment arms.

DISCUSSION AND CONCLUSION:

Among people 60 years or over receiving a hemiarthroplasty for an intracapsular fracture of the hip, the use of high dose dual antibiotic loaded cement did not reduce the rate of surgical site deep infection compared with standard care low dose single antibiotic loaded cement.