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Discontinuation of peri-operative gentamicin use for indwelling urinary catheter manipulation in orthopaedic surgery

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Abstract

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Methods The antimicrobial stewardship team of a 500 bed tertiary regional hospital performed a retrospective clinical study of gentamicin IDC prophylaxis around total hip and knee arthroplasties. Results were presented to the orthopaedic surgeons. A literature review identified no guidelines to support gentamicin prophylaxis and only a very low risk of bacteraemia associated with IDC insertion/removal in patients with established bacteriuria. Consensus was reached with the surgeons to discontinue this practice. Subsequent prospective data collection was commenced to determine effectiveness, with weekly feedback to the Department Head of Orthopaedics.

Results Data from 137 operations pre-intervention (6 months) were compared with 205 operations post-intervention (12 months). The median patient age was 72 years in both groups. Following the intervention, reductions in gentamicin use were demonstrated for IDC insertion (59/137 (42%) to 4/205 (2%), $P < 0.01$) and removal (39/137 (28%) to 6/205 (3%), $P < 0.01$). No gentamicin use was observed during the final 40 weeks of the post-intervention period. There were no significant differences between the groups for pre-operative bacteriuria, surgical site infections or acute kidney injury.

Conclusion A collaborative approach using quality improvement methodology can lead to an evidence-based reappraisal of established practice. Regular rolling audits and timely feedback were useful in sustaining change.

Disciplines

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Discontinuation of peri-operative gentamicin use for indwelling urinary catheter manipulation
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Short title

Gentamicin use in orthopaedic surgery

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Key words

Antibiotic prophylaxis, gentamicin, arthroplasty, indwelling catheters, surgical site infection

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Preliminary results from this study were presented at the Australian Society for Antimicrobials Annual Conference, Melbourne, Australia 2014

Abstract

Background:

Gentamicin has historically been used prior to insertion and removal of indwelling urinary catheters (IDCs) around elective joint replacement surgery to prevent infection; however, this indication is not recognised in the Australian *Therapeutic Guidelines: Antibiotic* and the paradigm for safe use of gentamicin has shifted.

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The antimicrobial stewardship team of a 500 bed tertiary regional hospital performed a retrospective clinical study of gentamicin IDC prophylaxis around total hip and knee arthroplasties. Results were presented to the orthopaedic surgeons. A literature review identified no guidelines to support gentamicin prophylaxis and only a very low risk of bacteraemia associated with IDC insertion/removal in patients with established bacteriuria. Consensus was reached with the surgeons to discontinue this practice. Subsequent prospective data collection was commenced to determine effectiveness, with weekly feedback to the Department Head of Orthopaedics.

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Data from 137 operations pre-intervention (6 months) were compared with 205 operations post-intervention (12 months). The median patient age was 72 years in both groups. Following the intervention, reductions in gentamicin use were demonstrated for IDC insertion (59/137 [42%] to 4/205 [2%], $p < 0.01$) and removal (39/137 [28%] to 6/205 [6%], $p < 0.01$). No gentamicin use was observed during the final 40 weeks of the post-intervention period. There were no significant differences between the groups for pre-operative bacteriuria, surgical site infections or acute kidney injury.

Conclusion:

A collaborative approach using quality improvement methodology can lead to an evidence based reappraisal of established practice. Regular rolling audits and timely feedback were useful in sustaining change.

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Introduction

Urinary catheterisation is common during the peri-operative period and is associated with increased risk of bacteriuria and symptomatic urinary tract infection (UTI).¹ In contrast, bacteraemia from indwelling urinary catheter (IDC) manipulation is rare, even when indwelling times are longer.²⁻⁴ A causal link has not been established between peri-operative asymptomatic bacteriuria, bacteraemia and subsequent haematogenous seeding of the prosthetic joint.⁵ Studies have reported either no effect⁶ or modest reduction⁷⁻¹³ in rates of bacteriuria and UTIs from antibiotic prophylaxis around short term IDC use. Several limitations applied: small sample sizes, none examined aminoglycosides, and the effect on antibiotic resistance was not routinely examined. In addition, the studies were not performed in the setting of orthopaedic surgery, and did not examine the impact on surgical site infections (SSIs).

Gentamicin is an aminoglycoside antibiotic administered intravenously for the treatment of Gram-negative infections.¹⁴ Gentamicin is also recommended as prophylaxis for surgery with high risk of Gram-negative infections, such as urological procedures.¹⁵ Due to concerns over side effects such as ototoxicity and nephrotoxicity, with even after a single dose,^{16, 17} there has been a shift in the paradigm of safe gentamicin use.¹⁸ Two recent studies examining the combination of gentamicin with a beta-lactam antibiotic for orthopaedic surgical prophylaxis gave conflicting results on the risk of acute kidney injury (AKI).^{19, 20} Both highlighted the presence of additional potentially nephrotoxic factors (e.g. older age, fractures, volume loss, anti-hypertensive medications and analgesics).

The Australian *Therapeutic Guidelines: Antibiotic*¹⁵ recommend against the routine use of gentamicin in the setting of peri-operative IDC insertion and removal and this recommendation has not changed in the latest update.²¹ Despite guideline recommendations, gentamicin had been used as peri-operative prophylaxis in around one third of orthopaedic patients in our hospital. Some surgeons were initially reluctant to

abandon gentamicin use, due to concerns about a potential increase in SSI rates and medico-legal considerations related to not following an established historical practice.

Education and quality improvement are fundamental aspects of antimicrobial stewardship (AMS) in hospitals.²² Recent evidence suggests that feedback as a component of the change management process is more effective when it is: frequently presented; delivered by a peer; and aims to decrease a specific behaviour.²³ Our study analysed the effect of education with rapid-cycle audit and feedback, a method that may be effective where clinicians have previously agreed to review their practice.²⁴ The importance of engaging with stable staff groups such as consultant surgeons and anaesthetists became evident. We assessed the impact of a group of interventions that aimed to reduce prophylactic gentamicin use during IDC insertion and removal in orthopaedic surgery, without increasing SSI rates. We aspired that this quality improvement initiative could constitute an effective model for management of change in the setting of limited background data.

Methods

Setting

We initially performed a retrospective clinical study at Wollongong Hospital, a regional 500 bed university teaching hospital in New South Wales (NSW), Australia. The antimicrobial stewardship (AMS) team (pharmacist and infectious diseases physician) identified the use of gentamicin as prophylaxis for IDC insertion and removal during a routine retrospective audit of systemic antibiotic prophylaxis around total hip and knee arthroplasties and revisions. IDC use was routine in this setting. The decision to administer gentamicin and its dose were at the discretion of the surgeon and there was not a departmental policy.

Intervention

This study employed Plan, Do, Study, Act (PDSA) quality improvement methodology²⁵. The timeline of observations and interventions is shown in Figure 1. The guideline recommendations for routine surgical prophylaxis were the same for both the pre- and post-intervention groups (cephazolin routinely, with or without vancomycin following risk assessment for methicillin-resistant *Staphylococcus aureus* [MRSA]).¹⁵ Notably, there was discussion with the surgeons and anaesthetists around guideline-concordant prescribing during the time interval (March 2012 to January 2013) from the presentation of initial findings until the main intervention point. Discussion also occurred at the AMS committee meetings (which included a surgeon representative) during this time.

SSIs were defined according to standard definitions²⁶ and reported by mandate to the NSW Ministry of Health. AKI was defined by the Kidney Disease Improving Global Outcomes criteria as a >50% rise above baseline serum creatinine.²⁷ Assessment for vestibular toxicity was available, as dictated by patient symptoms.

Outcomes

The effect of the intervention was assessed using the following measures: prevalence of gentamicin use for insertion and removal of IDCs; comparative SSI rates; proportion of patients with AKI 48-72 hours post-operation.

Data sources

A retrospective dataset of total hip and total knee arthroplasties was obtained from medical records for the period 1 January to 30 June 2011. Gentamicin use was assessed from anaesthetic and medication charts, and serum creatinine measurements were retrieved from the electronic medical record (eMR; Cerner Powerchart™). Arthroplasty data were collected prospectively during the post-intervention period (February 2013 to February 2014) from the eMR and ward list. The infection control service provided SSI rates.

Statistical analyses

Statistical analyses were performed using Stata statistical software: Release 14 (Statacorp LP, College Station, TX, USA). Chi-square and Fisher's exact tests were used as appropriate. A Shapiro-Wilk test was used to check for normal distribution, and Mann-Whitney U-test was used for continuous variables. Statistical significance was accepted as $p < 0.05$.

Ethics

This study was approved by the University of Wollongong and Illawarra Shoalhaven Local Health District Human Research Ethics Committee: HE11/103.

Results

Data from 137 operations pre-intervention (6 months, retrospective) were compared with 205 operations post-intervention (12 months, prospective; Table 1). Patient age and weight were similar in both groups; however, there were marginally more males in the post-intervention sample (31% vs. 42%, $p=0.048$). There were more positive pre-operative MRSA screening cultures in the pre-intervention group (3% vs. 0.5%, $p=0.047$). No differences were observed in the number of positive pre-operative urine samples (Table 1). Gentamicin doses ranged from 80mg to 240mg.

A significant reduction in gentamicin use was demonstrated post-intervention (Table 2). From week 12 of the post-intervention period (Figure 2), no further doses of gentamicin were administered for IDC manipulation.

No significant differences were found between the numbers of superficial hip, deep hip, superficial knee, or deep knee infections (Table 2). There were no significant changes in the rates of AKI, (Table 2) and no reports of vestibular toxicity following gentamicin use.

Discussion

Our study showed that a combined intervention of education and discussion with audit and timely feedback was effective in withdrawing the practice of prophylactic gentamicin for IDC insertion and removal in orthopaedic surgery. No significant changes were observed in the rates of SSI or AKI, although the study was not powered adequately to detect those. Most importantly, this study offers a model for a sustained quality improvement initiative in the setting of limited background data and contributes to emerging evidence on the beneficial role of AMS in improving antibiotic use.

The majority of infections in orthopaedic surgery are caused by Gram-positive skin flora, for which cephazolin and vancomycin (where appropriate) provide adequate prophylaxis.¹⁵ The potential risks and lack of clinical benefit from gentamicin in this setting formed the basis of our intervention. Rates of gentamicin use were reducing during the planning and discussion period, highlighting that the ongoing interaction resulted in gradual practice change. This was consolidated to a withdrawal of gentamicin prescribing in the study sample. The importance of directly addressing medico-legal concerns and providing written support for practice change was also recognised.

To our knowledge, this is the first study that has examined the impact of a change to IDC prophylaxis on clinical outcomes for orthopaedic surgery patients. A Cochrane review of antibiotic prophylaxis for short term IDC bladder drainage in adults showed that the primary outcome of bacteriuria was lower in the prophylaxis group.²⁸ There is no evidence linking insertion and/or removal of an IDC with Gram-negative bacteraemia and seeding of a newly implanted prosthesis. Although a recent study has demonstrated that asymptomatic bacteriuria was an independent risk factor for prosthetic joint infection, preoperative antibiotic treatment did not show any benefit and infecting organisms were frequently different to those isolated prior to surgery.⁵ Studies reporting bacteraemia from IDCs in the setting of chronic catheterisation reported low rates of established infection.²⁻⁴

There were no deep SSIs during the pre-intervention period and only one (0.5%) post-intervention. During the intervening period the SSI rate was low at 1.1%, comparable with existing literature.^{29, 30} These differences were not statistically significant. Studies powered to detect changes in SSI rates typically require larger sample sizes.²⁹⁻³¹

The rate of peri-operative AKI in our study was 1-2%. Rates have been previously reported at 11% for orthopaedic surgeries with routine gentamicin prophylaxis, but with different gentamicin doses.¹⁹ The lower rate in our study may be due to the lower doses of gentamicin for IDC prophylaxis than for routine skin prophylaxis.

A focus on immediate clinical outcomes (gentamicin toxicity) rather than parameters that appear later (antibiotic resistance) may have stronger influence on prescribing behaviour.³² Other strategies to reduce the risk of IDC-related UTI in the peri-operative setting include: intermittent or no catheterisation, early mobilisation (that shortens the period when the IDC needs to remain in place), training for insertion techniques, good IDC care and consideration of IDC materials.³³ Male patients receiving epidural anaesthesia may be at greater risk of urinary retention in the setting of orthopaedic surgery.³⁴⁻³⁶

There were several limitations to our study. These included confounding factors that may influence SSI rates (skin preparation, surgical technique, patient comorbidities) and the significantly larger proportion of male patients in the post-intervention sample (probably resulting from variation in data collection methods). The study was not powered to detect changes in SSI rates and those were not followed up long term, meaning that late deep infections may have been missed. The indication for gentamicin use was not routinely documented on the anaesthetic records and drug charts. The study did not follow the prescribing habits of individual surgeons, so some of the change in gentamicin use may have been due to changes in staff. There were; however, minimal staff changes at a senior level during study period. We believe that interpersonal interactions, the prevailing local culture of quality improvement and strong leadership of the units involved have contributed

to the successful outcomes of this study. Those features were furthermore strengthened during the interactive audit and feedback process; generalisability to other settings needs to be tested. Audiometry was not available on site to test for gentamicin toxicity. Although we used a methodology common in pragmatic AMS research, introduction of bias may be inherent, outside a randomised controlled environment.

In conclusion, we have shown that a group of robust multi-disciplinary AMS interventions effected durable practice change without obvious evidence of harm. Further studies are required to demonstrate validity in other settings, as well as the impact of gentamicin prophylaxis on renal function in other types of surgery.

Author disclosure statement

SB, CB, SJ – none to declare

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Table 1 Patient characteristics and pre-operative screening

	Pre-intervention	Post-intervention	<i>p</i> value
Median age, yrs (range)	72 (40-91)	72 (35-87)	0.79
Male, <i>n</i> (%)	43 (31)	86 (42)	0.048
Median weight[†], kg (range)	82 (40-142)	82 (44-143)	0.79
Cephazolin as skin prophylaxis[‡], <i>n</i> (%)	116/137 (87)	188/205 (92)	0.13
Hip arthroplasty[§], <i>n</i> (%)	58/137 (42)	70/205 (34)	0.13
MRSA screening swab positive	4/122 (3)	1/204 (0.5)	0.047
Pathogen isolated in pre-operative urine sample, <i>n</i> (%)	25/123 (20)	28/198 (14)	0.15
Pre-op positive urines treated with antibiotics, <i>n</i> (%)	11/25 (44)	8/28 (29)	0.24

[†]Data available from 133 patients pre-intervention; 202 post-intervention; [‡]Data available from 134 patients pre-

intervention, 205 post-intervention; [§]Includes revisions; ^{||}Includes mixed and single pathogen growth. The

remainder of the urine samples were reported as “no growth” or “no significant growth”.

Table 2 Gentamicin use, surgical site infections and acute kidney injury, *n* (%)

	Pre-intervention (6 months) n = 137	Discussion and planning period (20 months) n = 605	Post-intervention (12 months) n = 205	<i>p</i> value
Gentamicin for IDC insertion	59 (42)	N/A	4 (2)	<0.01
Gentamicin for IDC removal[†]	39 (28)	N/A	6 (3)	<0.01
Surgical site infections, deep	0 (0)	7 (1.2)	1 (0.5)	0.59
Surgical site infections, superficial	1 (0.7)	3 (0.5)	0 (0)	0.45
Post-operative acute kidney injury[‡]	2 (2)	N/A	1 (1)	0.35

[†]Data available from 137 patients pre-intervention, 204 patients post-intervention [‡]defined as >50% rise in baseline serum creatinine

Figure Legends

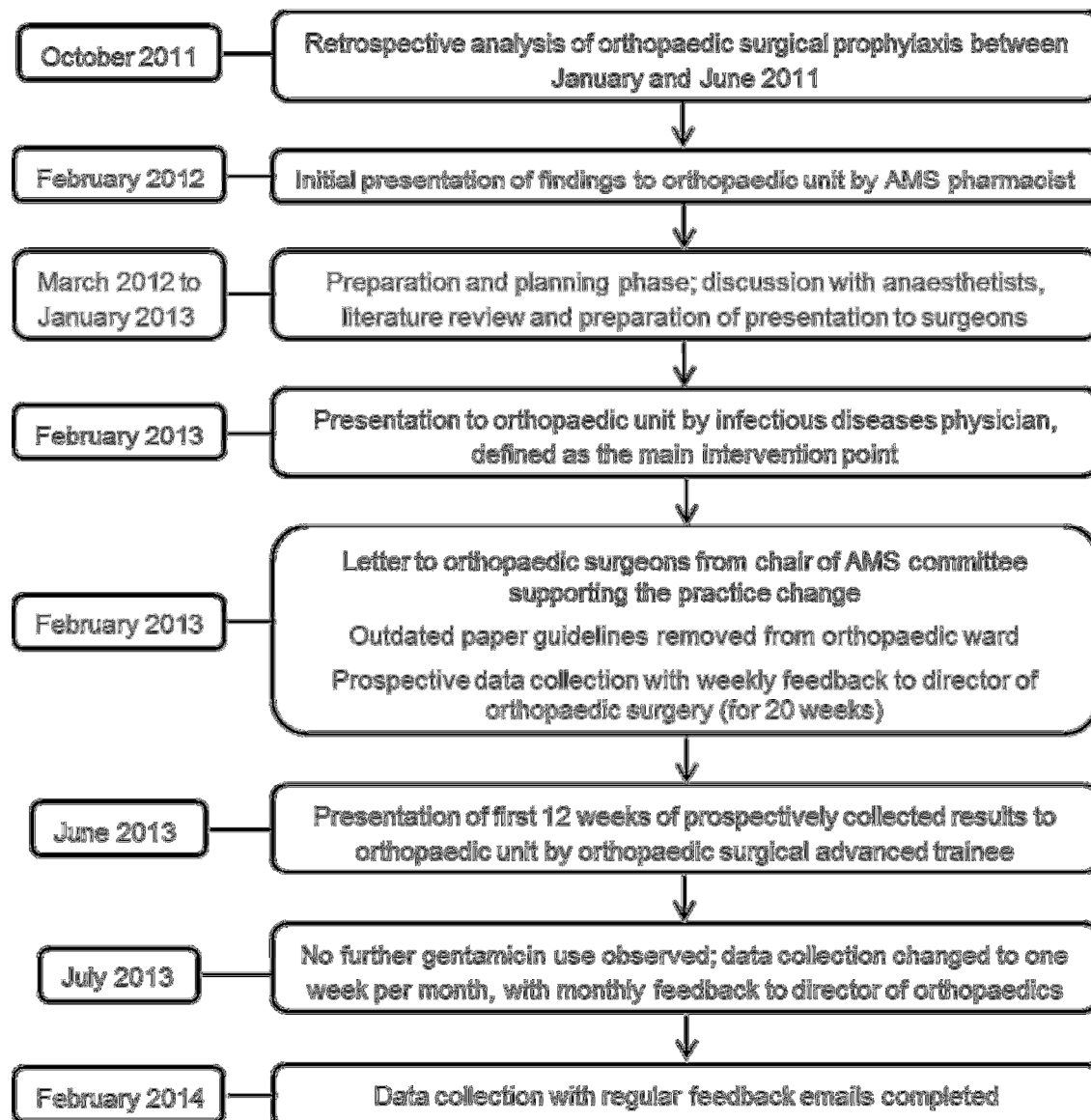


Figure 1 Timeline of observations and interventions

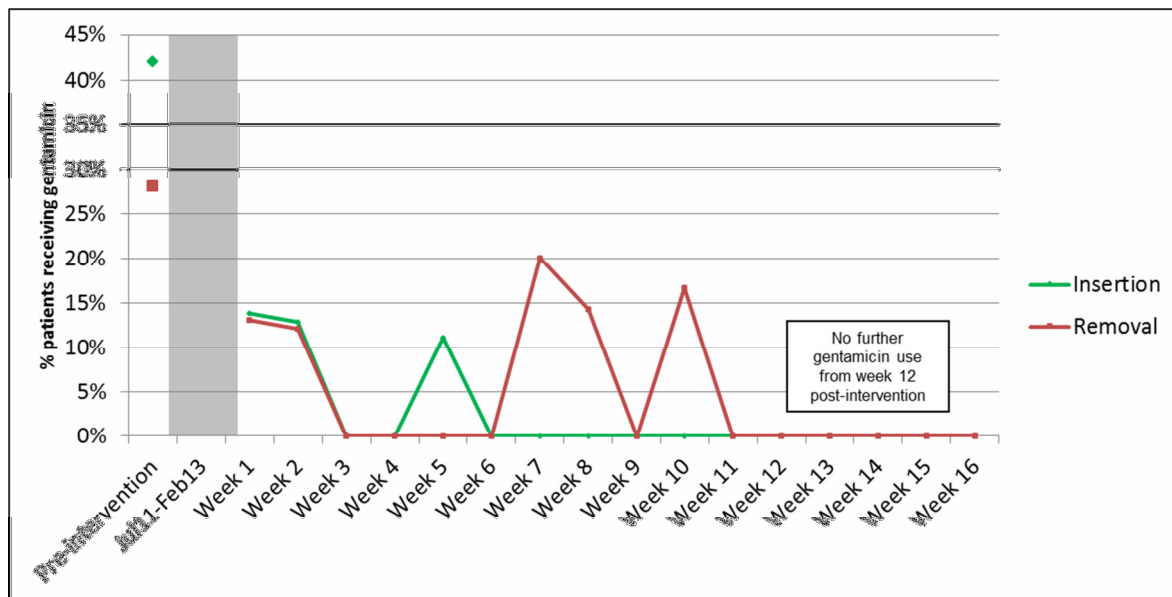


Figure 2 The proportion of patients receiving gentamicin for catheter insertion and removal over the 6 month pre-intervention period and during each week post-intervention. The discussion and planning period is shown in grey.