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Rationalising antibiotic use after low-risk vaginal deliveries in a hospital setting in India

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ABSTRACT

Background In 2017, a postoperative multidrug resistant case of urinary tract infection made obstetricians at Sitaram Bhartia Institute of Science and Research introspect the antibiotic usage in labouring mothers. Random case file reviews indicated overuse and variability of practice among care providers. This prompted us to explore ways to rationalise antibiotic use.

Methods A multidisciplinary team of obstetricians, paediatricians and quality officers was formed to run this improvement initiative at a private hospital facility in India. Review of literature advocated formulating a departmental antibiotic policy. Creating this policy and implementing it using improvement methodology helped us rationalise antibiotic usage.

Interventions We aimed to reduce the use of antibiotics from 42% to less than 10% in uncomplicated vaginal deliveries. We tested a series of sequential interventions using the improvement methodology of Plan–Do–Study–Act (PDSA) cycles, an approach recommended by the Institute for Healthcare Improvement. Learning from the PDSA cycle of the previous intervention helped decide the subsequent change ideas. The interventions included creation of a departmental antibiotic policy, staff engagement, and modification in documentation, concept of dual responsibility and team huddles as feedback opportunities. Information was analysed to understand the progress and improvement with change ideas.

Results Background analysis revealed that antibiotic usage ranged from 24% to 69% and average rate of antibiotic prophylaxis was high (42.28%) in low-risk uncomplicated vaginal deliveries. The sequential changes resulted in reduction in antibiotic usage to 10% in the target population by 4 months. Sustained improvement was noted in the following months.

Conclusion We succeeded in implementing a departmental antibiotic policy aligning it with existing international guidelines and our local challenges. Antibiotic stewardship was one of the first major steps in our journey to avoid multidrug-resistant infections. Sustaining outcomes will involve continuous feedback to ensure engagement of all stakeholders in a hospital setting.

INTRODUCTION

Problem description

In 2017 the surgical team at Sitaram Bhartia Institute of Science and Research (SBISR) was working on appropriate timing of antibiotic use to prevent surgical site infections. During an interdepartmental consensus meet, we realised that our department was often using triple antibiotics for a prolonged period even in elective caesarean sections.

Around the same time, a post-surgical patient developed multidrug-resistant urinary tract infection (UTI). Both the above incidents compelled us to introspect the appropriateness of antibiotic usage in our department. We thought of starting with the mothers with uncomplicated vaginal deliveries first, who had lowest risk of infection, to understand the magnitude of the problem. On random case file review over 2 weeks, we realised that antibiotics were given to almost all mothers who had an episiotomy and/or perineal tear. A detailed baseline data collection for a year revealed high usage of antibiotics for low-risk vaginal deliveries ranging from 24% to 69%. The decision of starting antibiotic was based on the primary care provider's discretion and not on any standard departmental protocol. The duration and type of antibiotic also varied as per individual provider. An informal discussion with stakeholders revealed a general lack of awareness regarding the adverse effect on neonates and long-term serious risks of resistance in community with indiscriminate use of antibiotics. An antibiotic stewardship plan in conjunction with the infection control policy needed to be put in place as a first step in our improvement journey.

Available knowledge

Antibiotics emerged as probably the most miraculous discovery of the 20th century in medicine. However, the dramatic increase in antibiotic resistance combined with the paucity of new drug development calls for their prudent, controlled and appropriate use in all areas of medicine.

Available data suggest that India has one of the highest rates of antibiotic resistance in the world, resulting from inappropriate use of antimicrobial agents.[1] The key factors leading to this are the unrestricted over-the-counter

availability of most antimicrobials and the lack of strict national guidelines to direct health workers, a system to ensure circulation of these guidelines and means to ensure adherence to them.[2–5]

A prospective cross-sectional observational study in Ujjain, India revealed that 87% of the women who had a vaginal delivery were prescribed antibiotics.[6] This was a cause of serious concern. Although the study included only 1077 women and did not involve any intervention, it postulated that specific policy and guidelines on how to prescribe antibiotics during delivery at healthcare facilities are needed. Another recent study in Kerala, India randomly allocated 170 low-risk labouring patients to antibiotic use and no antibiotic use after normal deliveries.[7] There was no observed significant difference in postpartum fever, wound infections and hospital stay. A similar randomised study in Mumbai, India involving 300 women also did not show any adverse outcome when antibiotics were not used.[8] The above studies show that written policy with strict adherence based on evidence could be successful in reducing antibiotic usage without any adverse effect. Another observational study used an administrative database over 10 years in the USA to analyse antibiotic use during delivery hospitalisations. Women were classified by mode of delivery and whether they had an evidence-based indication for antibiotics. Indications for antibiotics included preterm premature rupture of membranes (PPROM), caesarean delivery, group B streptococcus colonisation, chorioamnionitis, endometritis, UTIs and other infections. The proportion of women receiving unindicated antibiotics significantly decreased from 38.1% to 21.2% over a period of 10 years.[9] These findings indicate that evidence-based rationale for antibiotic use is becoming increasingly adopted into clinical practice in the USA. The study also showed that only having a standard protocol will not work. Widespread implementation will need change in physician practices and systemic changes to support the policy. This change in clinical practice may be beneficial in reducing antibiotic resistance, reducing risk of adverse reactions to unnecessary medications and may have important downstream health effects. WHO, other international organisations and national bodies including the Indian Council of Medical Research and Federation of Obstetric and Gynaecological Societies of India have clearly recommended against routine antibiotic prophylaxis for low-risk vaginal deliveries.[10–16] In contrast, Cochrane Review 2017 recommends that routine antibiotic use after uncomplicated vaginal delivery may reduce endometritis.[17] The Society of Obstetricians and Gynaecologists of Canada, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and Royal College of Obstetricians and Gynaecologists recommend against antibiotic prophylaxis even in operative vaginal deliveries.[11–13] However, ANODE trial showed benefit of a single dose of prophylactic antibiotic after operative vaginal birth and hence suggested that guidance from WHO and other national organisations should be reconsidered to reflect this.[18]

To preserve the effectiveness of current antibiotics, international health organisations have repeatedly highlighted the need to provide clear evidence-based guidance on their appropriate use.[19] Various strategies involving care providers, pharmacists and patients at the community level and hospital setting have been suggested to preserve the long-term utility of antibiotics.[20]

Rationale

We thought of starting a small and identified group of labouring mothers who were least likely to have infection. Antibiotics may be indicated in a variety of important obstetric conditions which put the woman or the fetus/neonate to an increased risk of contracting an infection. But with regard to the use of antibiotics in low-risk uncomplicated vaginal birth with or without episiotomy, the WHO has clearly recommended against routine antibiotic prophylaxis for such women.[10] Additionally, other various organisations clearly support the WHO recommendation too.[11–14]

When we realised that this group too had high antibiotic use, we held intradepartmental meetings with senior obstetricians and junior obstetricians first separately and then together to understand the reason for high usage (figure 1). We aligned their thoughts and ideas with the available literature to make a locally appropriate and easily acceptable plan.

Baseline measurements

An initial audit was planned spanning 1 year (February 2017–January 2018) from case records to understand and assess the problem. Background analysis excluded women with certain conditions which are known to be associated with increased risk of infectious morbidity or pre-existing infection. These exclusion criteria were: premature rupture of membranes (PROM), PPROM, instrumental delivery, third/fourth degree tears, undetermined antepartum haemorrhage, prolonged urinary catheterisation, gestational diabetes mellitus (GDM)/diabetes on insulin, manual removal of placenta and presence of a pre-existing systemic infection (such as UTI, upper or lower respiratory infections or fever). Out of 681 women delivered in our hospital during this period, 342 were uncomplicated vaginal births with low risk of infectious morbidity as per the above exclusion criteria. The rate of antibiotic prescription among these 342 women was calculated and the possible reasons were also noted. The analysis revealed that antibiotic usage ranged from 24% to 69% and the average rate of antibiotic prophylaxis was high (42.28%) in low-risk uncomplicated vaginal deliveries, which was not in accordance with standard international recommendations (online supplemental graph 1).

We did a quick verbal survey among the physicians to understand their perception on antibiotic usage in peripartum period in our hospital. The verbal survey indicated that physicians felt a written antibiotic policy will be useful and ensuring implementation will need regular sensitisation. This was followed by intradepartmental meetings to

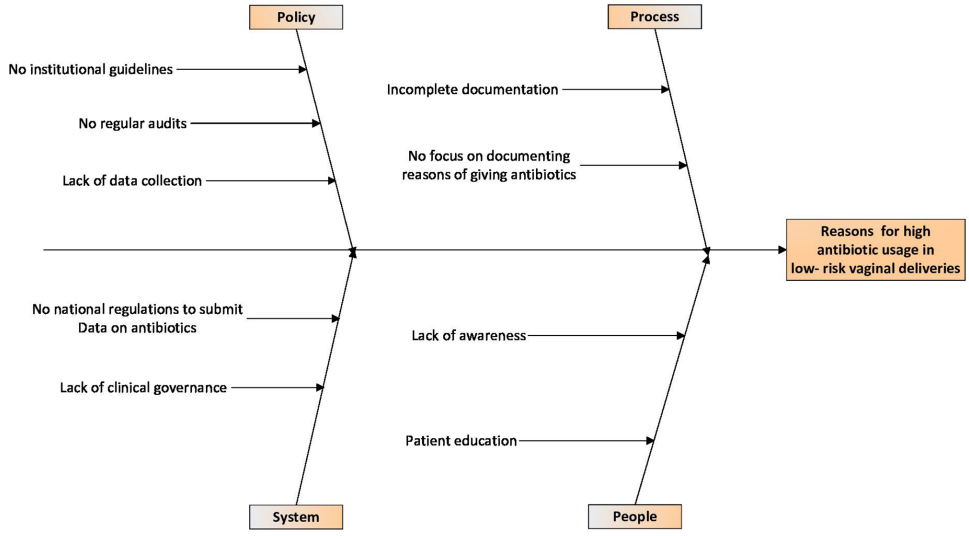

Figure 1 Reasons for high antibiotic usage in low-risk vaginal deliveries.

discuss this alarming rate of antibiotic prescription and to understand individual opinions regarding indications for its rationale use.

Specific aim

To reduce antibiotic use in low-risk uncomplicated vaginal deliveries from 42% to less than 10% in 4 months.

METHODS

Context

SBISR is a tertiary care 70-bedded hospital with a special focus on maternity care. We deliver around 800 mothers annually. We have three dedicated labour delivery rooms with nine labour ward nurses and five attending consultants and five senior consultants taking care of all labouring mothers as a part of group practice design. The senior and attending consultants work on rotation in the labour room and follow standard protocols. Patients are admitted under the unit rather than an individual doctor, hence the care and liability is shared. Clinical audits are a regular feature to share and introspect obstetric interventions like caesarean section, episiotomy and inductions. However, antibiotic usage in low-risk mothers was one area in which awareness was lacking as short-term harm of overuse was difficult to ascertain. In 2018, a multidrug resistant-complicated UTI in a postoperative patient compelled us to introspect and improve.

Earlier, the attending consultant witnessing and assisting delivery was primarily responsible for completing the labour-delivery record sheet apart from filling the medication charts. The rationale for giving antibiotics was primarily centred around individual understanding of the need for antibiotics. Lack of standard policy and unawareness of existing standard guidelines emerged as the most common contributory factor. For those who were aware of standard guidelines, lack of trust for applicability in our clinical scenario and undue fear of peripartum maternal or neonatal infection were felt as barriers. The choice of antibiotic was also variable. Habit, training and comfort in using antibiotics gave a sense of security to providers. Lack of awareness about the quantitative usage resulted in complacent attitude within the team.

Interventions

We formed a quality improvement (QI) team consisting of a senior obstetric consultant, an attending consultant, paediatricians, one quality consultant and a quality officer. Our intervention was the creation and introduction of an antibiotic policy for standardisation of care. Various national and international guidelines on antibiotic prophylaxis for women during labour and delivery were discussed in intradepartmental meetings. We reached a consensus and a departmental antibiotic prophylaxis policy was formulated stating 'no antibiotic usage in low-risk uncomplicated vaginal deliveries for the purpose of prevention of genital infection before, during or after labour (for 72 hours)'. The attending consultant of QI team together with the quality officer was assigned the work of collecting and analysing the data regularly.

Intervention #1: introduction of a departmental antibiotic policy in February 2018

The doctors in the obstetric team met and discussed the newly formulated departmental antibiotic policy and a copy was kept in the labour room protocol folder. The indications for antibiotic usage were PROM >12 hours, PPROM, instrumental delivery, third/fourth degree tears, undetermined antepartum haemorrhage, tears involving vaginal vault, prolonged urinary catheterisation, GDM/diabetes on insulin, manual removal of placenta and presence of a pre-existing systemic infection (such as UTI, upper or lower respiratory infections or fever). Though some guidelines recommend antibiotic prophylaxis in term PROM >18 hours, we decided to give it after 12 hours.[13] This was done as we felt that small and gradual change would be more realistic and acceptable in our

scenario. A second-generation cephalosporin with broad spectrum of action was chosen as first line of antibiotic if needed. It was mandatory to mention the indication for antibiotic prescription in every patient case record. Emphasis was given for strict adherence to the policy and a request was made for documentation in case record for any deviation from the protocol.

Plan–Do–Study–Act #1

The quality officer checked the case records every day in February 2018 and shared the data with the obstetricians. During this month, antibiotics were used in only 16% low-risk vaginal deliveries.

Plan–Do–Study–Act #2

We continued with the audit of case records fortnightly by the quality officer for the next month (March 2018). At the end of the month, 31% eligible women were administered antibiotics. This was higher than the rate of 16% we had achieved in February. It was felt that simply drafting the policy was not enough. It was equally important to ensure sustainability by circulating it effectively. So we planned to meet fortnightly to re-emphasise our goal, discuss the progress and consider revision in the original protocol based on challenges faced by the obstetricians. In one such meeting, we realised that the doctors were still sceptical about infection in cases of mild postpartum haemorrhage (PPH), anaemia, repeated per vaginal examinations, fragile and oedematous tissues and a few other nondescript clinical situations.

Intervention #2: modification of antibiotic policy in the beginning of April 2018

Plan–Do–Study–Act #3

To address the concerns arising from the policy, we did some more literature search. Based on our literature search and departmental discussions, we arrived at the conclusion that only women with PPH >1500 mL and those with moderate anaemia <8 gm% may be routinely given antibiotics in our set-up. Hence, a revised policy stating our antibiotic protocol, exclusion criteria and measures was drafted and circulated. We decided to reduce pelvic (PV) examinations to a minimum as a uniform consensus could not be reached on a figure beyond which one could define PV examinations to be multiple. Focus was to keep antibiotic usage to a minimum where consensus either remained divided and recommendations were not available. We instead opted to wait for our own data to build up further and then decide if we needed changes addressing these issues as a part of our antibiotic protocol.

Intervention #3: modification in labour and delivery record sheet and perinatal database in mid-April 2018

Plan–Do–Study–Act #4

Appropriate documentation in case records remained a challenge in analysing the accurate data. Every case record has a labour and delivery page (online supplemental annexure 1) in which details of the labour progress and outcome are noted manually. Perinatal data sheet (online supplemental annexure 2) on the other hand is an electronic database of our obstetric cases. We enter various parameters related to labour and delivery in the perinatal database and use it to analyse our clinical outcomes. In mid-April 2018, we made changes in labour and delivery page and perinatal database to document antibiotic usage with reason. The intention was to create a set format that would remind the obstetricians to write the reasons of using the antibiotics.

Additions to the perinatal database included the name of antibiotic prescribed along with indication, compliance to antibiotic policy (yes/no), number of women developing infections with the proposed antibiotic policy within 10 days of delivery and details of newborn having suspected/culture-proven neonatal sepsis, and whether the baby was given antibiotics or not. We collected data on perineal infection from the outpatient clinics during the postnatal visits.

The attending consultant present during the delivery was responsible for filling the above details in labour and delivery record as well as perinatal database. The attending consultant among the QI team supervised all the entries on a day-to-day basis. Details of perineal infection were updated after information by the consultant obstetrician. Neonatal infection and antibiotic details were taken from the nursery register and in cases of doubts cross-checked with the paediatricians and neonatologists. Analysis of our data for April 2018 showed a remarkable decline in the usage of antibiotic in our target population. Only 5% women were given antibiotics. The rate of perineal and neonatal infection was negligible which strengthened the obstetricians' trust in the protocol. Regular audits made us realise that compliance to our policy was critical and it has implications on the ongoing menace of widespread antimicrobial resistance.

Intervention #4: dual responsibility for antibiotic prescription in May 2018

In May 2018, the attending consultant involved in the QI project was leaving for further academic pursuit and a new peer champion took over. The new peer champion suggested that prescription of antibiotic as a dual responsibility could further serve as a checkpoint to discourage routine antibiotic administration in low-risk mothers.

Plan–Do–Study–Act #5

During a subsequent meeting on analysis of data, it was noted that the biggest challenges continued to be the nondescript clinical situations like deep episiotomy with friable tissues. It was then decided that any deviation from the prescribed antibiotic policy needed an approval of two senior consultants and these indications were earmarked to be discussed in forthcoming meetings. This dual responsibility further helped in reduction of antibiotic prescription. Analysis of our data for May 2018 revealed that only 10% women were given antibiotics.

Measures

Outcome measure: percentage use of antibiotics in low-risk uncomplicated normal vaginal deliveries.

Balancing measure: percentage of women developing perineal infections and percentage of neonates contracting infections with the proposed antibiotic policy.

Analysis

After implementation of the antibiotic policy in February 2018, we observed a drastic change in average compliance of antibiotic prescription in uncomplicated vaginal deliveries. Based on run-chart rules proposed by Anhoj and Olesen, we saw a shift in run on one side of the median, so we revised and calculated the new median.[21] Regular meetings and discussions helped the team identify, test, and implement genuine and timely interventions.

RESULTS

A run chart showing the percentage use of antibiotics in uncomplicated vaginal deliveries is presented in online supplemental figure 1. This is our outcome measure. We tested various interventions (annotated in graph) through several Plan–Do–Study–Act (PDSA) cycles and aimed at reducing the antibiotic usage in uncomplicated vaginal deliveries to not more than 10% women per month. Formulating and further acting in accordance with the antibiotic policy significantly shifted our median from 39.21% to 7.69%. The antibiotic prescription rate significantly reduced from annual average of 42.28% to 10% in May 2018. Average antibiotic usage since the initiation of our study has been 9%, 6% and 16% for 2018, 2019 and 2020, respectively. In 3 years, only 9 women out of 911 low-risk vaginal deliveries got perineal infections. Similarly, only 13 neonates out of the 913 babies were transferred to the neonatal intensive care unit due to sepsis. The percentage of women and neonates contracting infections with the proposed antibiotic policy has been negligible.

DISCUSSION

Summary

Antimicrobial resistance is a global public health challenge which has accelerated by the overuse of antibiotics worldwide. High rates of antibiotic prescription in our own hospital led us to introspect the need of a QI project to understand the challenges and ways to reduce it. We decided to formulate an antibiotic policy in line with existing international guidelines and adapted it to address our regional needs. To interpret appropriateness of use, we relied on measuring percentage usage of antibiotics in uncomplicated vaginal deliveries at low risk of infection first and followed it with PDSA cycles to suggest modifications on implementation of policy. Since we did not want to reduce antibiotic usage at the cost of increasing maternal and neonatal infections, we suggested changes in perinatal documentation to assess them as balancing measures. We achieved the aim within the planned timeline. The design of the plan was kept simple with sequential incremental interventions. The results made us understand that qualitative feedback, measuring and sharing quantitative outcomes can be useful for anyone attempting work in a similar setting. The lessons learnt and inferences drawn can be applied to other maternity care settings as well.

Interpretation

Interventions were implemented in a sequential manner to improve the appropriateness of antibiotic usage and simultaneously taking care that the stakeholders do not feel overwhelmed by multiple changes at one time. With first intervention of drafting a departmental antibiotic policy, we were able to see immediate gains in terms of reduced usage of antibiotic which had decreased from previous annual average of 42.28% to 16% in February 2018. The significant improvement was greatly satisfying to the core team. However, the second PDSA revealed increase in usage of antibiotics and this made us realise that sustaining outcomes is a bigger challenge. This compelled us to understand the fears and concerns of stakeholders and modify the protocol with further consensus meets.

A similar study clearly demonstrated that a focused educational programme for primary prescribers helped reduce the consumption of total inpatient antibiotics and specific antimicrobial agents within a short period.[22] Another study revealed that antimicrobial expenditures, which had increased by an average of 14.4% annually in the years preceding antibiotic stewardship programme implementation, decreased by 9.75% in the first year of the programme and remained relatively stable in subsequent years.[23]

Our study was successful in establishing a uniform antibiotic policy for vaginal deliveries. The antibiotic prescription rate significantly reduced during this timeline. We noted initial resistance leading to rejection of change ideas as some of our interventions interfered with physician autonomy. However, regular sharing of literature and emergence of drug-resistant infections in hospitals sensitised the caregivers and convinced them to pursue the common goal as a team. Team dynamics improved and we grew as a team with more confidence in our collective decisions.

Due to COVID-19, we saw a shift in median from 7.69% to 21.30% in the latter part of 2020. The pandemic led to a fear that other infections may supersede or concomitantly exist with no regular follow-up visits, thus doctors felt the need to administer antibiotics even in unindicated. Due to COVID-19, the team met less frequently to discuss their concerns and feedback regarding antibiotic usage. The pandemic had necessitated a modified roster system to cope with the crisis. This also meant less interaction with team members. However, we need to understand that practices may change in special situations and we must accept some variations. However, once the COVID-19 cases started declining in Delhi and

our hospital COVID-19 admissions reduced, we shifted our focus back on this QI initiative in December 2020. Small face-to-face meetings restarted with sharing of data. During COVID-19 months, our perineal infection data also suffered a setback due to irregular follow-up in the outpatient department (OPD).

The COVID-19 roster changed back to original roster from January 2021 which has helped the QI team to interact with most care providers on a regular basis. A more regular follow-up of patients in OPD will help us in procuring and disseminating perineal infection data (balancing measure) to our colleagues. The last PDSA which assigned dual responsibility to senior consultants for antibiotic prescription made us realise that specific consultants need repeated sensitisation to change due to their deep-rooted belief in safety of antibiotics, and unlearning for some care providers could be a continuous challenge to sustain our outcomes.

Lessons and limitations

Many lessons were learnt during our journey. The first lesson was that mere availability of guidelines or drafting a policy is not enough. Regular sensitisation is essential to achieve sustained results. Also before making a policy, it is pertinent to study the work environment and understand fears of frontline workers. We faced initial resistance from obstetricians as it was difficult to deviate from previous learning and practices. But as we reached good results within the stipulated time frame, we noticed a positive outlook to feedback discussions. Second lesson was that we need to integrate the policy in routine work so that it does not entail extra effort. In our case, filling up additional antibiotic-specific column in perinatal base became a routine practice requiring hardly any extra time. Positive results and even a small positive effort should be celebrated to boost the morale of the team. In due course of our study, the concept of peer champion evolved where local ownership with autonomy developed within the team. This became the backbone of the antibiotic stewardship of our team which resulted in sustainable outcomes.

One of the main limitations of our study was that the interventions were limited to the care provider and quality department. We hope to gradually involve our microbiology department and pharmacy in order to expand our pursuit. Together with a multidisciplinary team, an antibiotic protocol like ours can be further expanded to other departments. Another major limitation was the lack of patient education and sensitisation regarding policy of appropriate usage of antibiotics in our setting. Women were unaware of the reasons for receiving or not receiving antibiotics. Additionally, we restricted our policy to low-risk vaginal deliveries and have not yet expanded it further to include operative deliveries, though few guidelines recommend against usage in these cases as well.[11] The departmental antibiotic policy now awaits expansion to include more clinical conditions including emergency and elective caesarean sections. Lastly, estimation of balancing measures like perineal infection is a challenge as it is an OPD-based assessment. Accurate documentation relies on whether multiple caregivers give timely feedback to the QI team. We continue to seek fresh inputs and feedback within the team to address these limitations.

CONCLUSION

Educational interventions, institutional guidelines and hospital-based antibiotic stewardship programme are the need of the hour to stop the menace of antibiotic overuse. Our background data on high antibiotic usage even in mothers with low risk of infection prompted us to introduce interventions to reduce usage in this group first. But we soon realised that just introducing a change idea (antibiotic protocol) gave us initial success, but sustaining the good outcomes would entail regular sensitisation and addressing the concerns of stakeholders continuously. Small hospital settings like ours can replicate our initiative and learn from our challenges. We as a team now look forward to expand the scope of the study to other clinical areas as well.

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Contributors All authors contributed to this QI report. SB, SS, RS and YM planned and implemented the original QI project. SS, NK and YM collected and analysed the data. SS, RS and NK drafted the paper with SB. All authors contributed to the manuscript and approved the final draft.

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Patient consent for publication Not required.

Ethics approval This project was deemed to be an improvement project and not a study on human subjects. Therefore, ethical improvement was not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article.

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