Original Article

A quality improvement initiative to augment success rate of labour analgesia: interrupted time series analysis

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ABSTRACT

BACKGROUND

Standard operating procedures (SOP) for abour analgesia for parturients in Nepal are lacking. Labour analgesia programme was being conducted without a SOP in our institution. We identified that the success rate of epidural labour analgesia (ELA) was low. We developed standard operating procedures for labour analgesia services with the combined effort of the department of anesthesia and pain management with the department of obstetrics and gynaecology in Nepal Mediciti in 2019 January. SOP and troubleshooting protocol was implemented in 2019 February and this study was conducted to investigate the impact of programmed protocol for labour analgesia.

METHODS

An interrupted time-series analysis was performed as a process improvement project for all cases who demanded labour analgesia from November 2017 to December 2019 with retrospective data collection. The success of epidural labour analgesia was defined as vaginal delivery with Numerical Rating Scale for labour pain of 3 or less. The time series analysis intended to identify the change in the level of success rate (increase or decrease) and change in the slope of success rate over time.

RESULTS

The major problems identified by the team included lack of patient counselling, inadequate followup after the first dose of epidural, delay in attending call for labour analgesia by the anesthesiologist and undefined clinical pathways for the usage of drugs and troubleshooting. After implementation of the protocol, the interrupted time series showed a 24.77% relative increase in success rate with p value <0.001.

CONCLUSIONS

Interdepartmental group discussions, interviews with the patients and development of a team that worked on formulating SOP was done after problem identification. Patient counselling after 28 weeks of gestation gave patients time for psychological preparation and have realistic expectations regarding ELA than labouring parturients. Clear protocol regarding drug dosing and troubleshooting disposed interpersonal variation among the anesthesiologists. Continuous patient followup by the nurse-led team helped to identify any additional problems and address it and add on to the protocol. In conclusion, standard operating procedures guided epidural labour analgesia programme enhanced the success rate of epidural labour analgesia.

KEY WORDS

Standard operating procedure, Epidural analgesia, Labour analgesia, Quality improvement

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BACKGROUND

Labour analgesia helps alleviate the intense pain experienced during childbirth, promoting a more positive birthing experience for the mother1. Epidural labour analgesia (ELA) is one of the effective methods for pain relief during labour2. WHO recommends ELA for parturients 3. However, the exact rate of epidural analgesia in Nepal is unknown. Ladies are unaware of the ELA service and not all institutions can provide it due to stringent resources. A report showed that around 3-5% of labouring women at a few selected centres receive some form of pain relief4. In most institutions, labour analgesia is practised only on demand by the parturients.

We started a labour analgesia program that offered painless delivery to all pregnant ladies who visited the antenatal clinic at Nepal Mediciti in November 2017. As an institution dedicated to provide safe and quality care, we started monitoring the success of the program from the very beginning. We defined successful Epidural Labor Analgesia (ELA) as vaginal delivery with a Numerical Rating Score of <3. The success rate of epidural labour analgesia (ELA) in our institution was inconsistent (figure 3).

With insights gained from the data analysis, we developed standard operating procedures (SOPs) using the modified Delphi technique, training healthcare professionals on the latest practices, and ensuring consistent adherence to the revised procedures for administering epidural analgesia during labour. Since January 2019, we have executed upgraded SOPs at our institution, incorporating feedback from healthcare practitioners and monitoring patient outcomes. Meanwhile, we collected performance metrics, such as successful ELA, patient feedback, and any unexpected issues encountered during the implementation of the upgraded SOPs to continuously refine and improve the procedures. Our aim was to increase the success rate of epidural labour analgesia to > 90% within 3 months of implementation of Standard Operating Procedure.

METHODS

We designed an observational study, an interrupted time series analysis conducted over a period of 25 months, as a quality improvement initiative at Nepal Mediciti Hospital, a tertiary care center in Kathmandu, Nepal. We retrospectively collected data for success rate from November 2017 to December 2019 for success rate and other measures. We evaluated the low success rate of ELA through discussion and brainstorming sessions. We realised that variable drug concentration, drug administration time, elaborated patients' chimaera for complete painless labour, inconsistent patient follow-up, high nurse turnover in the labour ward, and cynical obstetrician due to bitter patient experience were the reasons for our failure. The Fishbone diagram helps us understand and comprehend the problem. Subsequently, the team devised the idea of standardising the process, leading to the development of a Standard Operating Procedure (SOP). The SOP incorporated patient counselling at 28-34 weeks of gestation; six monthly trainings for nurses in two batches; uniform drug dose, concentration, and timing for administration; and continuous patient follow-up to amend and reform it accordingly. Data were collected from January 2019 to December 2019 to examine the effects of the prepared SOP.

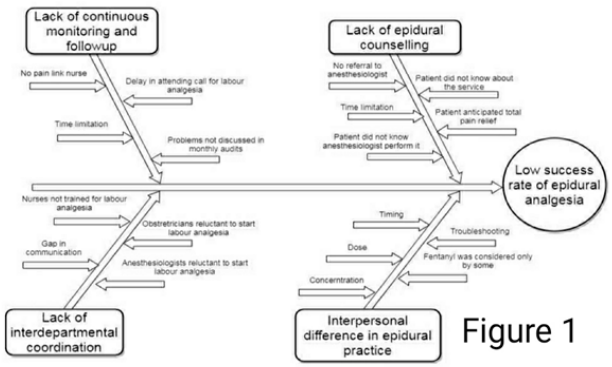

Figure 1

We developed a team comprising obstetricians, anesthesiologists, labour nurses, and pain-link nurses supported by the hospital leadership team. An SOP was formulated and presented to the team in batches of two in our institution's weekly continuing medical education (CME) session. The team trained six nurses in two batches for labour epidural analgesia. Due to the high nurse turnover in the institution, we have six monthly brush-up sessions to keep up with the team. Newly joined nurses received bedside training from the existing nurses. The team leader explained the team dynamics, organisation, and role of each member.Some Patients were oblivious to ELA services. Some expected complete pain relief during labour.

After 28-34 weeks of gestation, we counselled the patients for psychological preparation and had realistic expectations regarding ELA. We explained them regarding the numerical rating scale, advantages, and disadvantages of epidural analgesia and set the expectations.

All patients who required ELA were included in this study. Once labour was started and the cervix was dilated 1-4 cm, obstetric registrar on duty made a labour analgesia call to anaesthesiologists on duty. The anesthesiologist on duty attended the call within 30 min, took informed consent and administered labour epidural. A large-bore cannula 18-16G was kept in place before administering the ELA. The ECG, SpO2, and NIBP monitoring was performed at the time

of insertion and continued until removal of the epidural catheter. The NIBP was monitored every 5 min.The level of epidural insertion was L3-L4 or L2-L3 in the sitting or lateral position.

After negative aspiration of the blood and CSF, any drug was administered via the epidural route. A test dose of 3 ml 2% lidocaine with adrenaline (1:200,000) was administered at the end of uterine contraction.

The initial loading dose consisted of 11 ml normal saline plus 0.8 ml (40 µg) Fentanyl plus 3.2 ml of 0.5% plain Bupivacaine with a total volume of 15 ml resulting in a concentration of 0.106% Bupivacaine fentanyl 2.6 micrograms per millilitres.

Maintenance dose consisted of 10 micrograms (0.2 ml) Fentanyl plus 4.8 ml of 0.5% plain Bupivacaine plus 15 ml of normal saline, a total of 20 ml (0.12% Bupivacaine 0.5 micrograms per millilitres) should be prepared and 10 ml is given as a bolus each hour after the loading dose.

If the Numerical rating scale was >3 after 20 min of loading, 5 ml of the maintenance dose solution was prepared. If the pain is not relieved, an additional 5 ml of the maintenance dose solution is administered after a lockout interval of 20 min. Even if pain is not relieved, the epidural catheter position is checked if it is misplaced or leaking, and reinsertion is considered.

Motor function of the patient was assessed hourly. If motor weakness in the limbs is observed after the maintenance dose, the local anaesthetic concentration is reduced by half.

If ELA had to be abandoned, fentanyl was continued in patient-controlled analgesia.

A 50 µg loading dose of fentanyl and 20 µg boluses with a lockout of 5 min and a maximum dose limit of 240 µg h−1 were used. All parturients were instructed to press the bolus button whenever they required pain relief. They were told to press the button as often as they felt necessary, and it was explained that each pump was programmed to monitor the total dose administered, and that safety limits were set to avoid an overdose. This implies the possibility that not every request would be rewarded, and the PCA device was discontinued at full cervical dilatation.

Continuous patient follow-up by the pain management team helped to identify any additional problems, address them, and add to the protocol.We used a learning health-system model for the transformation process. (Figure 2)

Figure 2

We studied the success rate of ELA. Interrupted time series analysis was used to see whether observed outcomes were due to the intervention.Structural measures included formulation and regular upgrade of the SOP using a learning health system model, educating the ELA team regarding the same and designated pain rounds for patient feedback and documentation.The process measures included attending labour epidural analgesia calls by an on-duty anesthesiologist within 30 min, percentage of patients counselled during 28-34 weeks of period of gestation and percentage of patients receiving standardised concentration of epidurally injected drug. The outcome measures included vaginal delivery with a Numerical Rating Scale for labour pain of ≤ 3 as successful epidural labour analgesia.

RESULTS

Thirty patients were retrospectively analysed from November 2017 to January 2019 before SOP was introduced. 119 patients were counselled after SOP implementation. Of the 107 patients who opted for ELA, 6 underwent caesarean delivery for obstetric reasons, so they were excluded from the study. 101 were enrolled, 2 had leaking epidural catheter and 1 had displaced catheter. The remaining patients had successful ELA.

After implementation of the protocol, we collected the data and performed an interrupted time series.

The X-axis in figure 3 shows the time interval and y axis shows the success rate in percentage. The green arrow shows the time of SOP implementation. After implementation of the protocol, the interrupted time series showed a 24.77% relative increase in success rate with p value <0.001. Success rate increased from previous 72.25 percent to 97.02 percent.

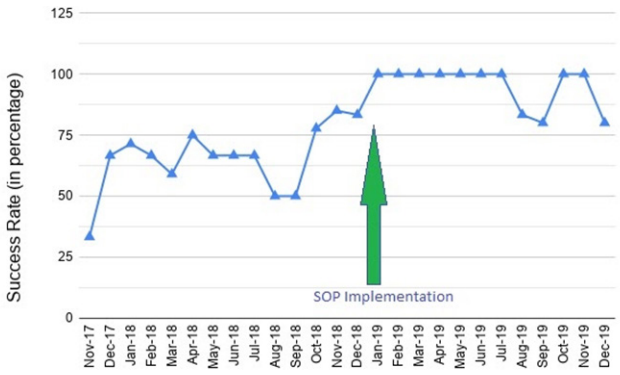

Figure 3

We included all parturients who demanded labour analgesia. Patients who developed an allergic reaction to local anesthetics were excluded from the study.

We found that lack of epidural counselling, interpersonal differences in epidural practice, lack of interdepartmental coordination, and continuous monitoring and follow-up were the reasons for our setbacks. (Figure 1)

Interdepartmental compliance, patient awareness and tolerance to pain were contextual elements that interacted with the intervention

Additional manpower and time in order to train nurses, interdepartmental and patient meetings were the cost associated with the intervention

DISCUSSION

Our study showed 24.77% increments in the success rate of ELA after implementation of the SOP and adoption of a learning health system model. The model comprised data collection for knowledge and used it to improve performance, then again quantified performance into data, see the changes, and amend accordingly5. The pain link nurse was specially designated to gather data and patient feedback, and presented it to monthly audits.

We ensured that all patients who visited the obstetrics outpatient department at 28-34 weeks of gestation underwent counselling regarding labour analgesia. She was given information about the entire process and the numerical rating scale. She would be counselled that it would not be completely pain-free, so she would have realistic expectations regarding analgesia.

Whenever a patient opted for labour epidural, she was asked if she was counselled during 28-34 weeks of gestation. If counselling was missed, the attending nurse/doctor would fill continuous quality improvement forms and notify the team. The time taken by the attending anesthesiologist after the epidural analgesia call was recorded. Any delay of more than 30 minutes was flagged and notified to the team. Any deviations from the protocol were recorded. The patients were followed up after successful vaginal delivery for their experience and feedback. All of these are addressed by monthly audits. Any changes needed in the protocols were discussed and informed by the team.

The application of standard operating procedures (SOPs) for labour epidural analgesia and its success in quality improvement within a learning health system model highlights the following points.

1. Standardisation of Procedures: SOPs play a crucial role in standardising the delivery of labour epidural analgesia, ensuring consistency in care and minimising variations among practitioners6,7.
2. Enhanced Patient Safety: The implementation of SOPs contributes to improved patient safety by reducing the likelihood of errors or deviations from established best practices during the administration of labour epidurals8.
3. Quality Improvement Metrics: The use of SOPs facilitates the measurement of key quality improvement metrics, such as pain relief effectiveness and complication rates, allowing for the continuous monitoring and enhancement of care processes9.
4. Training and Education: SOPs serve as valuable tools for training healthcare professionals, ensuring that practitioners are well-versed in standardised protocols, leading to more proficient and confident application of labour epidural analgesia 10.
5. Data Collection and Analysis: SOPs contribute to systematic data collection in a learning health-system model. Analysing these data helps identify trends, areas for improvement, and evidence-based adjustments to SOPs to optimize outcomes over time11.
6. Adaptability to Evolving Practices: SOP is designed to allow for periodic review and updates in response to emerging evidence, technological advancements, or changes in clinical guidelines, ensuring that the procedures remain aligned with the latest best practices12.
7. Collaborative Learning Environment: We emphasise the importance of a learning health system model, where feedback from practitioners and real-world experiences contributes to the iterative refinement of SOP, fostering a collaborative and adaptive approach to care delivery 13.
8. Patient-Centred Care: SOPs designed with a patient-centred approach have enhanced the overall childbirth experience by addressing individual needs and preferences while maintaining safety and quality standards. This study selected the best treatment for patients among the available interventions for the best outcome[14].

The SOP utilised an optimised process for care, implemented the best evidence-based medicine, improved continuing medical education, improved induction of new hospital staff, integrated quality control, transparency and enhanced protection from malpractice15.

ADVANTAGES

1. Continuous identification and troubleshooting problems
2. Constantly updated protocol
3. Interdepartmental integration
4. Review of existing evidence and impact of the intervention
5. Involvement of the multidisciplinary team for both designing and endorsing intervention
6. Multifaceted nature of the intervention aimed at tackling the problem from several angles
7. The piloting and consequent adaptation of the intervention

CHALLENGES

1. Additional human resources allocation
2. Schedule for data collection, meeting, training, new protocol amendments

LIMITATIONS

1. Before and after comparison
2. Selection bias
3. Data is organisation specific
4. The small sample size and non-randomized nature of this study limit its generalizability.
5. It requires additional human resources (pain link nurses) for monitoring and data collection in places where electronic medical records are not accessible.

The learning health system model was used to sustain the project and make it more continuous. Electronic medical records or pain-link nurses serve as the infrastructure to make it sustainable.

This model is highly scalable, as it has elements that are available in most centres in low middle-income countries like Nepal. Leadership commitment is something that might be lacking to provide labour analgesia services as a priority thing.

Patient satisfaction and an increased success rate boosted the team morale to continue the program despite the additional need for manpower and time constraints due to meetings and continuous follow-up.

REFERENCE

1. Hodnett ED. Pain and women's satisfaction with the experience of childbirth: A systematic review. American Journal of Obstetrics and Gynecology. 2002 May;186(5):S160–72.
2. Lam K, Leung MK, Irwin MG. Labour analgesia: update and literature review. Hong Kong Medical Journal. 2020 Sep 17;
3. WHO recommendations: Intrapartum care for a positive childbirth experience Web annex. Evidence base [Internet]. Available from: https://iris.who.int/bitstream/handle/10665/260215/WHO-RHR-18.04-eng.pdf?sequence=1
4. Shrestha, B., Devgan, A. & Sharma, M. Effects of maternal epidural analgesia on the neonate - a prospective cohort study. Ital J Pediatr 40, 99 (2014). https://doi.org/10.1186/s13052-014-0099-x)
5. Pomare C, Mahmoud Z, Vedovi A, Ellis LA, Knaggs G, Smith CL, et al. Learning health systems: A review of key topic areas and bibliometric trends. Learning Health Systems. 2021 Mar 18;
6. Chen C, Kan T, Li S, Qiu C, Gui L. Use and implementation of standard operating procedures and checklists in prehospital emergency medicine: a literature review. The American Journal of Emergency Medicine. 2016 Dec;34(12):2432–9.
7. International Conference on Harmonisation. [last cited on 2010 Nov 20]. Available from: http://www.ich.org/
8. Croteau RJ, Schyve PM. Proactively error-proofing health care processes. Error Reduction in Health Care: a systems approach to improving patient safety. 2000:179-98.
9. Albaadani MM, Bataweel AO, Ismail AM, Yaqoob JM, Asiri ES, Eid HA, et al. Ten Quality Improvement Initiatives to Standardize Healthcare Processes [Internet]. www.intechopen.com. IntechOpen; 2024. Available from: https://www.intechopen.com/online-first/1175730
10. Ente C, Ukpe M. Standard Operating Procedure. Springer eBooks. 2022 Jan 1;23–37.
11. Leotsakos A, Zheng H, Croteau R, Loeb JM, Sherman H, Hoffman C, et al. Standardization in patient safety: the WHO High 5s project. International Journal for Quality in Health Care [Internet]. 2014 Apr 1;26(2):109–16. Available from: https://academic.oup.com/intqhc/article/26/2/109/1803803/
12. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet (London, England) [Internet]. 1993 Nov 27;342(8883):1317–22. Available from: https://www.ncbi.nlm.nih.gov/pubmed/7901634/
13. Easterling D, Perry AC, Woodside R, Patel T, Gesell SB.

Clarifying the concept of a learning health system for healthcare delivery organizations: Implications from a qualitative analysis of the scientific literature. Learning Health Systems. 2021 Jul 22;6(2).

14. Levitan SE, Schoenbaum SC. Patient-centered care: Achieving higher quality by designing care through the patient's eyes. Israel Journal of Health Policy Research [Internet]. 2021;10(1):1–5. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7934513/

15. Sathyanarayana Rao T, Radhakrishnan R, Andrade C. Standard Operating Procedures for Clinical Practice. Indian Journal of Psychiatry [Internet]. 2011;53(1):1. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056180/