



Original Research Article

Drug use pattern in the labor room and adherence to standard treatment guidelines: A prospective cross-sectional study in a tertiary care teaching hospital

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ABSTRACT

Introduction: Labor is the natural process which varies greatly in duration, severity and for the risk involved to the mother and the fetus. Hence this study was planned to study drug use pattern in the labor room and the extent of adherence of prescribers to standard treatment guidelines available.

Objectives: To study the drug use pattern in the labor room and adherence to the standard treatment guidelines.

Result: A total of 302 patients were included. Mean no. of the drugs prescribed to the patients was 4.63. The most commonly used drug in the labor room was Oxytocin followed by Pantoprazole (Proton Pump Inhibitor) and Cefotaxime (Antibiotic) Regarding adherence, complete adherence was observed in ACOG Guidelines for induction of labor as well as cervical ripening and dilatation. Around 25.8% adherence was seen in WHO guideline for cervical dilatation and ripening. No adherence was observed for RCOG Guidelines for Tocolysis and AWHONN for Analgesia. 2.3% adherence to SOGC guidelines for prevention of PPH, thus, considering 302 cases- only for use of Misoprostol and Methyl Ergometrine. In 300 patients, SOGC guidelines regarding the use of Oxytocin for prevention of PPH were not adhered to.

Conclusion: Guidelines are adhered to different extents, high or low in the patient population, which also points to the fact that national guidelines are the need of the hour.

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1. Introduction

Labor is the natural process by which a fetus of viable age is expelled from the uterus, to begin its extra uterine existence. It varies greatly in duration, intensity and in the risk involved to the mother and the fetus. The fetus commonly presents as a vertex presentation, and labor starts spontaneously and terminates naturally, without any artificial aid and without complications to be labelled as normal labor in retrospect.¹ Childbirth by its very nature carries potential risks for the woman and her baby, regardless of the route of delivery. To ensure that labor is smooth, progressive and less painful, various drugs are available and extensively used to aid the process of labor.

Various drug groups used in the management of labor include: Drugs for cervical ripening, induction and augmentation of labor, drugs for pain relief (analgesics), for prevention and treatment of Post-partum hemorrhage and drugs for prevention and treatment preterm labor.

This study was planned to evaluate the drug use pattern in a labor room of a tertiary care public hospital in a developing country like ours. The prescription audit in the labor room throws light on and smoothen out the process and significantly decrease the chances of complications. There are various specific guidelines for rational use of drugs on the induction and augmentation of labor, for the pain relief, for the prevention and management of post-partum hemorrhage and the management of preterm labor, to be used in the labor room. These guidelines are devised to ensure rational use of drugs and help in safe delivery of

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term fetus with minimal complications.

Since there is paucity of standard Indian guidelines, our data will generate a baseline trend of drug use pattern with clinical correlation and the study result will stimulate the formation of Indian guidelines for the drug usage in labor room.

2. Objectives

1. To study the drug use pattern in the labor room
2. The adherence to the treatment guidelines will be evaluated as per the standard guidelines mentioned above.

3. Materials and Methods

A prospective, cross sectional study was carried in the labor room at tertiary care teaching hospital, for the two months of May and June 2015, after ICMR approval, and approval from the Institutional Ethics Committee and Hospital. Written informed consent was taken from the patient. Data was collected from the patient who fulfilled the following inclusion and exclusion criteria.

3.1. Inclusion criteria

Patients admitted in the labor room for the purpose of delivery at the tertiary care teaching hospital were enrolled into the study.

3.2. Exclusion criteria

1. Patient unwilling to give consent for the study
2. Patients undergoing operative delivery.

3.3. Sample size

This was a duration based study, so total enrollment was completed in two months duration of May- June 2016. All the patients admitted to labor room were enrolled after explaining the aim of the study.

Data was recorded in a case record form, containing patient's demographic details like name, age, sex, address, socio-economic class, past history, family history provisional and final diagnosis, and complete prescription was noted. The prescription given to the patient including the drug prescribed, dose, frequency and duration of the treatment was noted on the case record form. For the drugs prescribed by the brand names, the generic names of the drugs and generic contents of each formulation was obtained from commercial publications like Indian Drug Review- 2015. Further, the drug prescribing pattern of each aspect of delivery was evaluated using the standard treatment guidelines. (Table 1)

3.4. Statistical Analysis

The data was entered in Microsoft Excel 2010 and SPSS version 21.0 was used to calculate the demographic, clinical data and drug prescribing indicators.

4. Results

A total of 302 female patients were enrolled in the study. The mean age: 23.92 ± 4.02 years. Majority were below 30 year (95.03%). As far as the chief complaints are concerned, majority of the patients complained of abdominal pain (16.89%) and leaking PV (16.56%). Many patients presented with more than one complaint. 6.29% females presented with co-morbid illnesses along with pregnancy. Majority of the patients were multigravida 67% and rest of the patients were primi gravida. Majority of the patients were having singleton pregnancy (57%). (Figure 2) Since majority of the women were primi patients, they had no previous abortions. A total of 138 patients were anemic. Most common blood group was B+ in 82 patients, total Rh Negative were 15 patients.

Majority of 97% percent patients presented with cephalic presentation on abdominal examination.

4.1. Drug prescribing pattern

A total no. of drugs prescribed were 1395. Mean no of the drugs prescribed to the patients: 4.63. (Figure 3) A minimum of 3 drugs are used in a patient in the labor room, irrespective of her labor status. (except preterm labor). Most commonly used drug in all the patients was Oxytocin. Betamethasone (according to the WHO guidelines): is used to enhance lung maturity in preterm babies. Most of the primi patients were given episiotomy to easy the process of labor and Lignocaine 1% was administered for the purpose of local anaesthesia. Most common route for drug administration was intravenous (IV).

4.2. Guidelines adherence-Induction of labor

In this study, 242 patients had spontaneous onset of labour, 60 needed induction of labour ;

4.3. ACOG guidelines

4.4. NICE guidelines

NICE- Guidelines-suggesting intravaginal Dinoprostone gel; instead any other method is not followed. Hence, this guideline was not adhered to in any of the patient as intracervical Dinoprostone gel .

4.5. Guidelines adherence-Cervical Ripening

Thirty one patients out of 302 had unfavorable cervix. So, drugs for cervical ripening were administered. In 8 patients;

Table 1: Standard treatment guidelines used as reference

Stage/process of Labor	Guidelines
Induction and augmentation of labor	American College of Obstetricians and Gynecologists (ACOG). ²
Cervical ripening	NICE guidelines, 2008 ³ WHO recommendations ⁴
Labor analgesics/anesthesia	American College of Obstetricians and Gynecologists (ACOG). ⁵
Tocolysis	Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) ⁶
Prevention of Postpartum Hemorrhage	Royal College of Obstetricians and Gynaecologists (RCOG) ⁷
Treatment of Postpartum	The Society of Obstetricians and Gynaecologists of Canada. ⁸ WHO recommendations for the prevention and treatment of postpartum hemorrhage. ⁹

Misoprostol administered according to WHO guidelines for cervical ripening were followed in patients

Thirty patients were induced with Drotaverin and Valethamate bromide, regimens which did not follow any of the above guidelines. Drugs used in these patients were given Drotaverine & Vathemate bromide, Estradiol.

4.6. ACOG

100% adherence to ACOG Guidelines, in patients who required cervical ripening. 31 Patients were administered the Dinoprostone gel and in 8 patients Misoprostol was administered which completely followed the guideline.

4.7. Guidelines adherence-tocolysis

Three patients out of 302 patients had preterm onset of labor and were treated with Tocolytics. Beta-agonists Isoxuprine; Intravaginal progesterone suppositories and Allylestrenol. In none of these patients the RCOG guidelines were followed.

4.8. Guidelines adherence- Analgesia

Contramol and Phenargan were used, not according to the AWHONN guidelines. For analgesia; injection Tramadol and Promethazine along with additional effect of Drotaverine were administered. Contramol was used in 13 patients, Phenargan used in 12 patients whereas the 1% Lignocaine was used in 101 patients as a local anaesthetic.

4.9. Guidelines adherence-Prevention of PPH

Prevention of PPH was exercised in almost all the patients; SOGC Guideline: 10 units Oxytocin in 1L saline; was not followed in any case. In 8 patients, tablet Misoprostol 600-800mcg; in addition to Oxytocin infusion intravaginal, according to SOGC guidelines were given.

4.10. Guidelines treatment of PPH adherence

Two patients had PPH, and treatment of PPH was given in accordance with the WHO guidelines.

5. Discussion

The well-being of the child and the mother, decreased fetal and maternal morbidity and mortality rates are the ultimate goals, for the attainment of which these protocols have been formulated. A study by Ma 'asoumah Makhseeda et al. showed the trends of drugs used in labour in Kuwait. Which was a drug survey of a total of 326 mothers was conducted in the labour room of the Maternity Hospital, Kuwait. Data were collected from the prescription sheets and patient files as similar to our study. Result showed high usage of analgesics, H2 receptor blockers and tranquilizers constitute the most commonly used drugs in labor.¹⁰ A study prospective done by Leimel A. et al done by the delivery room study of 100 women admitted to the delivery room, the authors assessed the quality and quantity of drug use During labor and after-delivery. An assessment of the quality of drugs employed. Therapy Involves the use of well-tolerated and non-toxic drugs administered in doses routine to relax pregnant women, facilitate delivery, complications and adverse prevent prevention.¹¹ There is a paucity of data in literature in this area. So, our study is one of its kind. No studies regarding adherence to various guidelines for the management of patients in the labour room was found.

Labor is a very crucial period for the pregnant mother as well as her child to be born. It is the culmination of the nine months of anticipation, preparation and care. To ease this very crucial process, various drugs are used, which significantly help in reduction of the maternal mortality rate and the neonatal death rate and also make the process of labor more bearable. Since these drugs along with having a positive therapeutic effect also have some side effects and toxicity, guidelines have been formulated to optimize the therapeutic effect and minimize the adverse effects. Guidelines ensure rational and optimal use of these drugs. Hence, it becomes all the more important to adhere to these protocols for the sake of safety of the mother and the child.

A total of 302 patients admitted to the labor room were studied according to the above mentioned protocol. The mean age of the patients was 23.92+- 4.08 YEARS, majority of women fell in the Age group of 21-30 yrs which is also the age of active reproductive function. Around, 37% of the

Chief Complaints

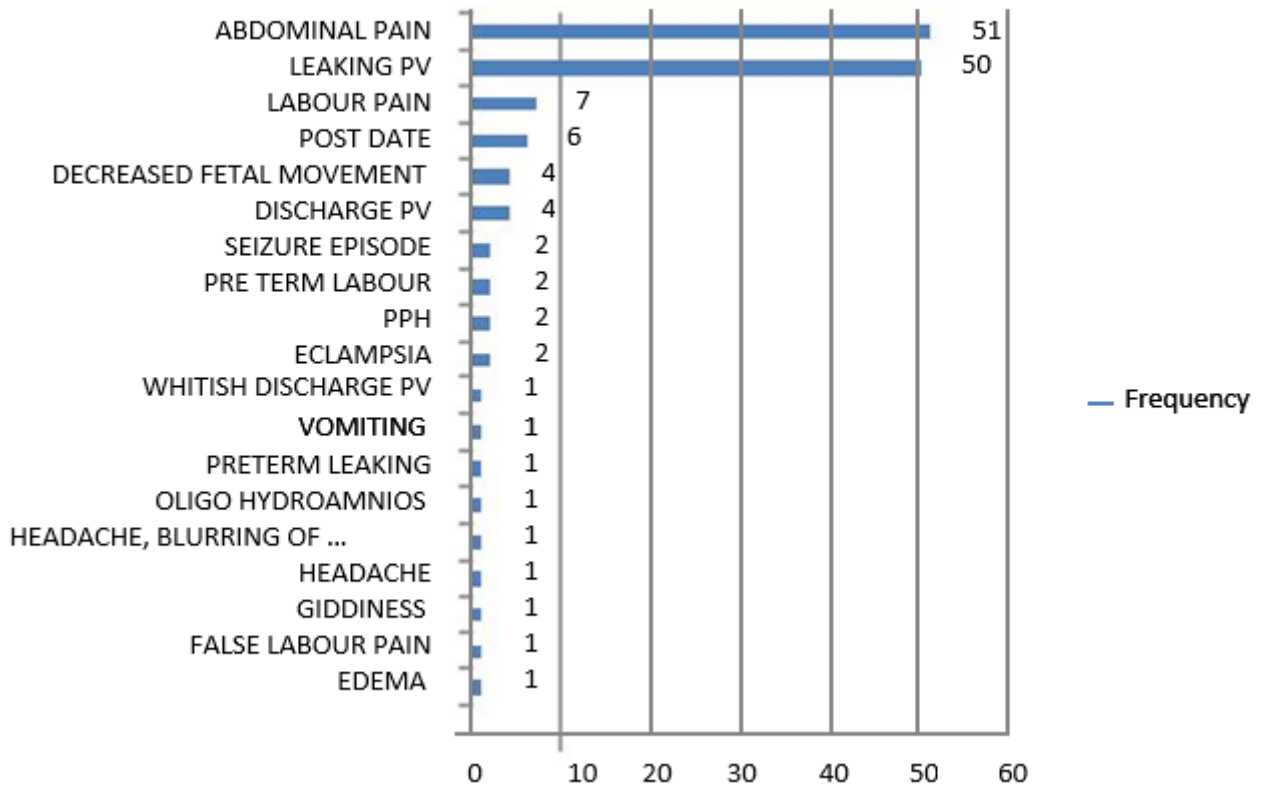


Fig. 1: Presenting complaints

Obstretic History- Parity

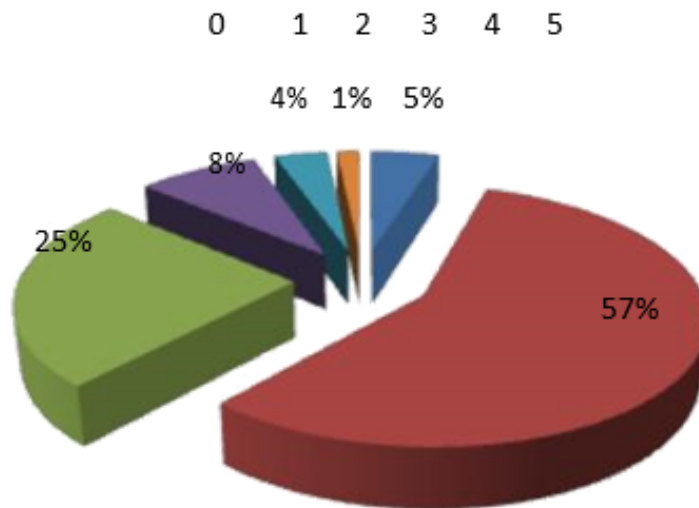


Fig. 2: Obstretic history: parity

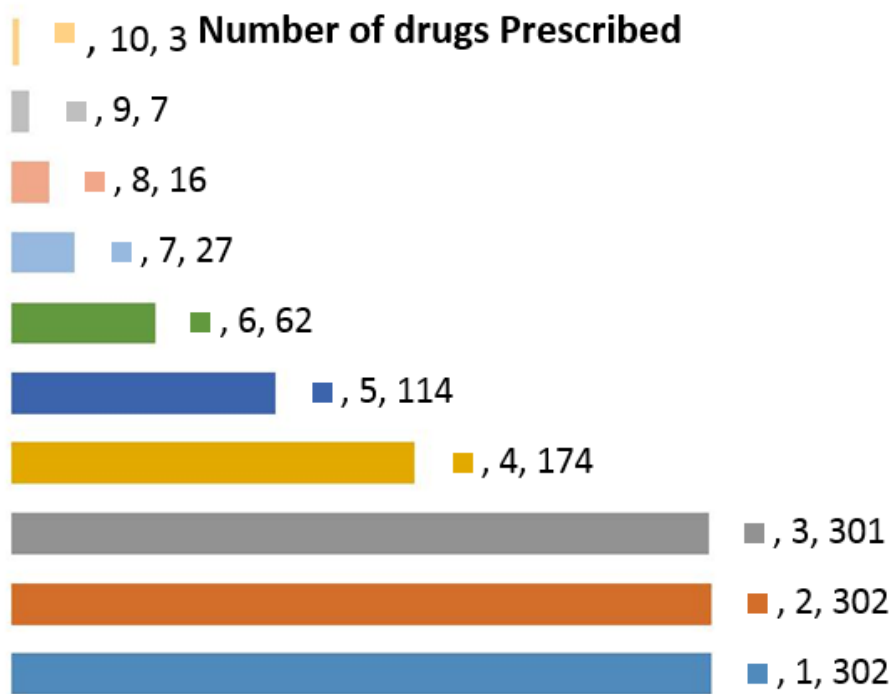


Fig. 3: Frequency of the drugs prescribed

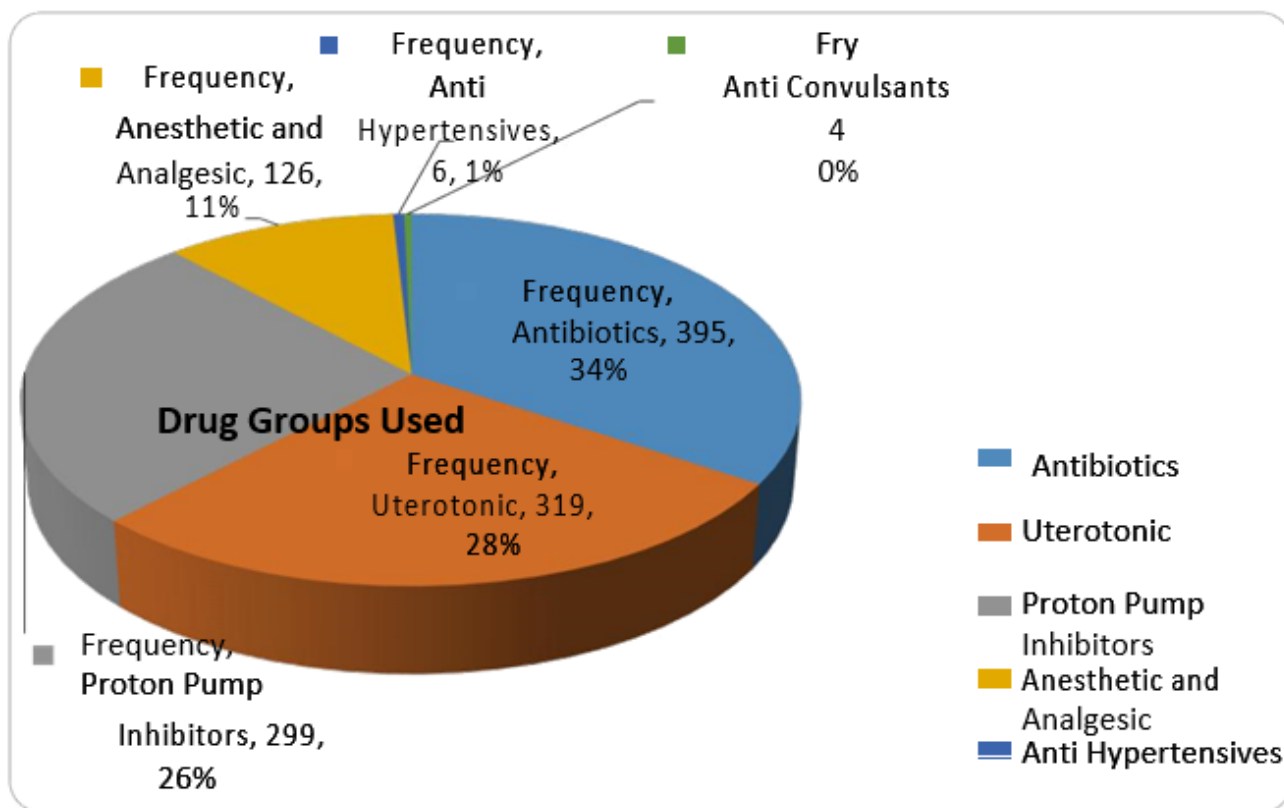


Fig. 4: Most commonly prescribed drug groups

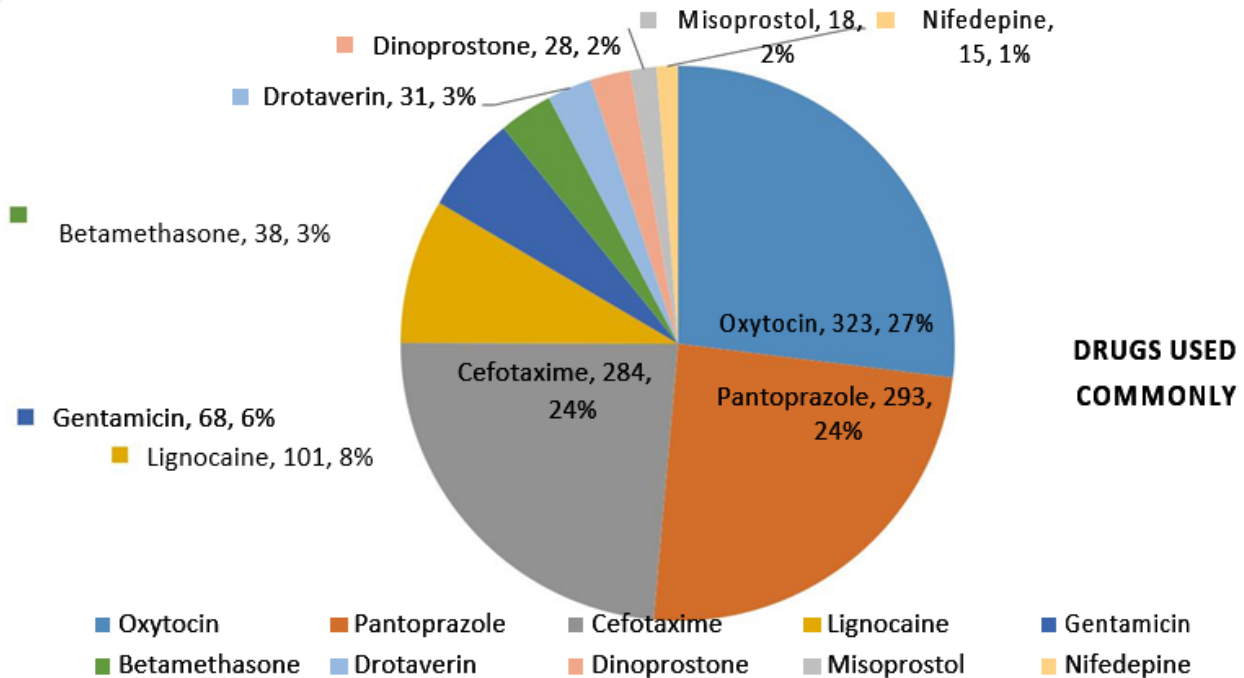


Fig. 5: Drugs used commonly

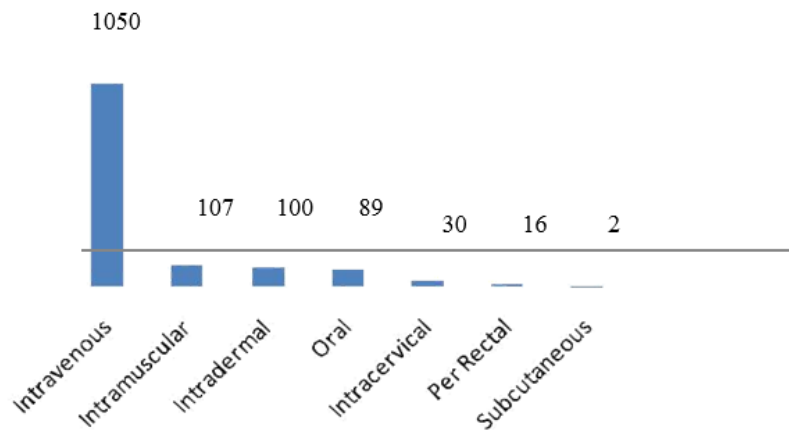


Fig. 6: Route of drug administration

patients were primigravida.

Total number of drugs administered-1395

Mean no of the drugs prescribed to the patients: 4.63

A minimum of 3 drugs were used in patients in the labor room, irrespective of their labor status. (except preterm labor). Most commonly used drug group was antibiotics in the form of Cefotaxime, which is a 3rd generation cephalosporin followed by Gentamicin which is an aminoglycoside. These two antibiotics were given as a blanket cover in the peripartum period for prophylaxis against infection. Although it is not strictly indicated in this situation, looking into the hygiene and nutrition status of

the patient. This adds to the additional cost burden to the hospital as well as increased chance of development of drug resistance.

Most commonly used drug as auterotonic was Oxytocin in all the patients. Oxytocin is preferred over Ergometrine and prostaglandins because of two reasons. First being the fact that it has a short half life and via a slow IV infusion intensity of the action can be well controlled and action can be terminated quickly. Low concentration of Oxytocin allows normal relaxation in between concentration and fetal oxygenation does not suffer. Most common route for drug administration was intravenous (IV). An antibiotic

Table 2: Adherence to guidelines

Guidelines	Adhered	Non-adhered	Percentage adherence
Induction of labor (ACOG)	60	0	100%
	Oxytocin, Misoprostol, Dinoprostone		
Induction of labor (NICE)	0	302	0
	Oxytocin+Misoprostol	Oxytocin	
Cervical ripening (WHO)	8	23	25.8%
	Misoprostol	Drotaverine and Valetamate	
Cervical ripening (ACOG)	31	0	100%
	Misoprostol and Dinoprostone gel		
Tocolysis (RCOG)	0	3	0%
	Nifedipine and Atosiban	Isoxsuprine (beta agonist) and progesterone	
Analgesia (AWHONN)	0	126	0%
	Contramol and phenargan	Lignocaine	
Prevention of PPH (SOGC)	7	295	2.3%
	Misoprostol and methyl Ergometrine	Oxytocin 40-80 IU is used instead of 20-40 IU	
Treatment of PPH (WHO)	2	0	100%
		Oxytocin/ergometrine/PG	

(Cefotaxim); Proton Pump Inhibitors (Pantoprezole) and Oxytocin was used in all the patients included in the study.

Oxytocin was used for three indication:

1. Induction & Augmentation 20% patients
2. Prevention of PPH {99.9%}patients
3. Cervical Ripening

Almost all the patients received Proton Pump Inhibitor in the form of Pantoprazole. None of the guidelines advocate this use as a routine practice, this drug is probably prescribed for GIT Prophylaxis, these is because of the fact the normal labor is a stressful situation and patients more or less remain nil by mouth . Over and above there is a risk of gastritis because of administration of antibiotics.

5.1. ACOG guidelines

Adherence for induction of labor was completely followed and adhered to in all 60 patients who required induction of labor. Dinoprostone [PGE2 analogue] was used to induce labor in 31 (out of 60 induced pts). Misoprostol[PGE1 analogue] was used for induction of labor in 10 ; Oxytocin was used in 21 patients for inducing labor out of the total 60 induced patients. More than 1 drugs were used in a few patients for the same indication.

5.2. Nice guidelines for induction of labor

NICE Guidelines for Induction of labor were not followed.

According to the NICE Guidelines for Induction of labor- Oxytocin iv alone should never be given for induction of labor. Also, the Misoprostol should be given intravaginally and Dinoprostone should only be used in case of intrauterine death.

5.3. Cervical ripening and dilatation

31 patients required cervical ripening and intracervical Dinoprostone gel was used. This shows 100% adherence to ACOG Guidelines.

Misoprostol was used for cervical ripening in 8 patients; WHO and ACOG guidelines for cervical ripening were followed.

More than 1 drugs were used in a few patients for the same indication. Other drugs to aid cervical dilatation were Drotaverine and Valetamate. These were used in 31 pts out of (302); as an aid for cervical dilatation. None of these drugs are suggested in the standard guidelines like ACOG and WHO.

As far as ACOG and WHO Guidelines for cervical ripening is concerned it was followed to a large extent reflecting good prescribing practice and infrastructural support to facilitate the same.

5.4. Tocolysis

As far as tocolysis is concerned this data is insufficient to comment on the adherence. Only 2 patients received tocolytic therapy with beta 2 agonist and hence RCOG guidelines were not adhered to. RCOG guidelines recommends the use of calcium channel blocker Nifedipine and Oxytocin antagonist Atosiban. Atosiban which is a new drug suppresses premature contraction, with less cardiovascular complications as compared to beta 2 agonist, however it is not available in India. In future, it holds promise as a tocolytic looking into its benefit-risk ratio.

5.5. Prevention of PPH

In 7 cases, guidelines for prevention of PPH were followed where in Misoprostol and methyl Ergometrine were used; in 300 patients, SCOG guidelines regarding the use of Oxytocin for prevention of PPH were partially adhered to with respect to the doses of the drugs given.

5.6. Treatment of PPH

Two patients had PPH, and treatment of PPH was given in accordance with the WHO guidelines which recommends intravenous Oxytocin; if additionally required iv Ergometrine, Oxytocin-Ergometrine fixed dose or a Prostaglandin drug. Hence, 100% adherence to WHO guidelines in patients with PPH.

5.7. Analgesia

Contramol and Phenargan were used. Local anesthetic used was 1% Lignocaine, which is not according to the AWHONN Guidelines. No adherence seen.

In our study the most commonly used drug groups are antibiotics, the H2 receptor blocker and the uterotonics, whereas in the study done in Kuwait by Ma'asoumah Makhseeda et al. showed high usage of analgesics, H2 receptor blockers and tranquilizers. In our set-up, the use of tranquilizer is not common as the previous study. This study is a unique study providing an insight into the practical aspects of working of a busy labor room, in a tertiary care teaching hospital. Thus, it also gives an idea of the actual ground situation. Extensive data has been collected and analyzed, thus giving a substantial base to the study. Guidelines used to check adherence i.e. those used here for reference are standard guidelines laid down by various reputed international organizations. Different Guidelines used in this study as no indigenous guidelines are available, so we have to depend on the guidelines developed in the medically developed nations. Also, the various guidelines have been chosen according to the availability of drugs in our setup, also according to the feasibility of administration and monitoring of particular drug; the more relevant guideline was selected for the

study. Each and every aspect of the process of labor has been covered under this study beginning with induction of labor and cervical ripening to tocolysis to prevent preterm delivery; treatment and prevention of post partum hemorrhage which is a common complication after delivery. Also the drug prescribing pattern in tertiary care teaching hospital, suggests extensive use of drugs for prevention i.e. prophylactic use and therapeutic purposes

The Limitations of this study: The strength of the study could have been increased if maternal and fetal parameters may be correlated. The reasons for non adherence on the part of the prescriber could have been sort into via interviewers, face to face discussion or questionnaire.

One reason which the authors feel for the selection of the drug on the part of the prescriber is also guided by the local factors for example availability of the drugs in hospital pharmacy. All these drugs need to be made essential if adherence is expected in government run tertiary care hospital. Further studies in this regard can throw more light on the subject.

The guidelines here are pertaining only to the drugs used in the labor. Guidelines for other co-morbid conditions have not been considered here, as it is beyond the scope of this study. Further Cost-effectiveness studies can be planned in the department using various guidelines.

6. Conclusion

1. A total of 302 patients recruited in the study. Majority of women fell in the 21-30 yrs
2. Most prescribed drug group : Antibiotic. Most commonly used drug in the patients was Oxytocin.
3. Mean no of the drugs prescribed to the patients : 4.63
4. Hence, 100% adherence to ACOG Guidelines was seen in 60 patients who required induction of labor
5. NICE guidelines for Induction of labor was not followed at all.(0%)
6. Around 25.8% adherence was seen in WHO guideline for cervical dilatation and ripening, where only 8 patients received Misoprostol out of 31 patients with unfavorable cervix. .
7. Complete adherence (100%) was seen for ACOG guideline for cervical ripening and dilatation which mentions use of Misoprostol and Dinoprostone gel for the same.
8. No Adherence (0%) to the RCOG Guidelines for Tocolysis as in our set up we use Isoxsuprine(beta agonist) and progesterone. According to RCOG Guidelines, Nifedipine and Atosiban has been recommended.
9. No Adherence (0%) to the AWHONN for Analgesia. In our set-up, 1% Lignocaine is used for episiotomy.
10. 2.3% adherence (7 patients) to SOGC guidelines for prevention of PPH, which recommends the use of Misoprostol and Methyl Ergometrine ; thus, considering

302 cases- only for use of Misoprostol and Methyl Ergometrine.

11. In 300 patients, SOGC guidelines regarding the use of Oxytocin for prevention of PPH were not adhered to, as the dose recommended for iv infusion is 20-40IU in 1000ml. And in our set-up upto 40-80IU in 1000ml is used. Hence, guidelines not strictly followed. Some patients were given more than 1 drug for the same indication. Hence, this guideline was only partially adhered to.
12. Two patients had PPH, and treatment of PPH was given in accordance with the WHO guidelines which recommends intravenous Oxytocin; if additionally required iv Ergometrine, Oxytocin-Ergometrine fixed dose or a Prostaglandin drug. Hence, 100% adherence to WHO guidelines in patients with PPH.

7. Summary

No adherence was seen for induction of labor (NICE GUIDELINES), Analgesia in labor (A Whonn Guidelines) and for Tocolysis (RCOG Guidelines). Only Partial Adherence to the SOGC Guideline for Prevention of PPH. Complete Adherence was seen for Induction of labor (ACOG), for Cervical Ripening (ACOG) and for Treatment of PPH (WHO)

8. Suggestions

Obstetric analgesia which is the most important part of obstetric practice, which is well developed in western countries which is not practice well in developing country because of lack of infrastructure, in the form of fetal electronic monitoring, availability of drug delivery system like infusion pump.

Cost-effectiveness studies can be planned in the department using various guidelines.

A hospital/ departmental protocol/guidelines should be made for induction of labor, cervical ripening, tocolysis, analgesia, prevention and treatment of labor.

Future study comparing the outcome in two groups i.e. one who follows the guidelines and the other where guidelines are not followed; can be taken up.

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11. Conflict of interest

None.

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