Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

Study of Single Dose versus Multiple Dose Antibiotic Prophylaxis in Electiveceasarean Section

Meghna Treesa Antony, RituBawa, K.Rukmini*

Department of Obstetrics &Gynaecology, Sree Balaji Medical College & Hospital

Affiliated to Bharath Institute of Higher Education and Research, Chennai, Tamil Nadu, India.

Corresponding author e-mail id:rukmini.k@bharathuniv.ac.in

ABSTRACT

To compare the effectiveness of single dose antibiotic prophylaxis and routine multiple dose antibiotic prophylaxis, with regards to postoperative infective complications, in patients who are undergoing elective caesarean section. Reduction in the number of doses of antibiotics will reduce the chances of emergence of drug resistant strain of bacteria and also prevent unnecessary drug exposure to vast majority of patients. The single dose antibiotic is safe, effective, convenient and economical. And it is better in case of low risk and routine cases of caesarean section.In this era of rising antibiotic resistance, lesser usage of antibiotics has become the need of the hour and this study has given positive reinforcement towards the same direction. It is concluded from this study that the single dose prophylactic antibiotic is equally efficacious as multiple dose prophylaxis in elective uncomplicated caesarean section. There was no statistically significant difference noted between the two groups when compared in terms of febrile morbidity, wound induration, serous wound discharge, purulent wound discharge, wound gaping, uterine involution, UTI or abnormal vaginal discharge.

Keywords:
Liverdiseases,Steroidtherapy,Diabetesmellitus,Tuberculosis,HypertensionandAnaemia

1.INTRODUCTION

Caesarean section over the past few decades has been emerging as one of the most common surgical procedures worldwide considering its continuously increasing trend both in developed as well as developing countries. Even though for certain medical indications, caesarean

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

sections are deemed as safer route when compared to vaginal delivery, in the absence of the medical requirement the risk of the procedure outweighs the benefits. In fact, the women undergoing caesarean delivery has 5-20-fold greater risk of infectious complications when compared to those who are delivering vaginally1,2.

Given the worrisome trend of increasing caesarean delivery, measures for reducing the infectious complications like fever, endometritis, urinary tract infections and wound infections, has gained utmost importance and is an important area of focus.3Traditional principles of skin antisepsis, thorough and sterile surgical techniques and antibiotic prophylaxis has been proven effective against infectious complications associatedwith any surgeries3. Even though the American Congress of Obstetricians and Gynaecologists (ACOG) recommends the use of single dose antibiotic prophylaxis for caesarean sections4, in a developing country like India where patients are from lower economic strata, nutritionally challenged and with lesser educational background, the effectiveness of single dose antibiotic protocol has to be tested and proved, in order to reduce the general apprehension among consultants in using lesser amount of antibiotics.4,5

Maternal death during labour and in the puerperium is a cause of concern for the health care personnel and governments alike. Other than obstetric haemorrhage, eclampsia and obstructed labour, puerperal sepsis is one of the leading causes resulting in maternal mortality in India along with obstetric haemorrhage, prolonged obstructed labour and eclampsia. Despite advances in various modality of treatment like diagnosis and antimicrobial therapy, it still remains a prominent contributor to MMR. Although it might not lead to the death of the mother puerperal sepsis remains a major cause of long-term morbidity including chronic pelvic pain secondary infertility and ectopic pregnancy.6,7

Increased cost of medical care and increased demands of hospital beds is giving added impetus to search for newer methods to decrease postoperative morbidity and shorten the duration of hospital stay. The purpose of this study is to examine infectious morbidity comparing single and multiple dose of same intervention to assess the regime which is optimal for antibiotic prophylaxis in caesarean section and also to assess the cost effectiveness in both regimes.8

2.MATERIALS AND METHODS

STUDY DESIGN: Comparativestudy.

PERIOD OF STUDY: From September 2017 to March 2019for a

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

duration of 18months.

PLACE OF STUDY: Department of Obstetrics and Gynaecology, Sree Balaji Medical College and Hospital, Chromepet, Chennai, India.

PARTICIPANTS: This study included 200 participants, randomized into two groups of 100 each. The participants were selected based on the inclusion and exclusion criteria.

INCLUSION CRITERIA:

1. Women undergoing elective caesarean section in Obstetrics and Gynaecology department of SreeBalaji Medical College andHospital.
2. Women with regular antenatalcheck-up.
3. Women who are willing to participateinthe study and areconsenting.
4. Uneventful antenatalperiod.
5. Antenatal mothers with no historyofpre-existing medical illness and no history of antibiotic treatment 2 weeks prior tosurgery.

EXCLUSION CRITERIA:

1. Patients who underwent emergencyLSCS
2. Patients with a history of adverse drug reaction to cephalosporingroup
3. Patients admitted for elective LSCS with medical disorderslike
    - Renalimpairment
    - Liverdiseases
    - Steroidtherapy

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

- Diabetesmellitus
- Tuberculosis
- Hypertension
- Anaemia

4. Patients with pre-pregnancy BMI>25
5. Patients admitted for placenta previa, PROM,PPROM
6. Any antibiotic treatment 2 weeks prior tosurgery.
7. Patients with HIV, who underwentrenal transplant or in any immunocompromised state will beexcluded
8. Prolonged preoperativehospitalization

STANDARD DEFINITIONS

- Febrile morbidity: Oral temperatureof>38.0oC (100.4" F) persisting for at least 24 hours, excluding the first 24-hour postoperatively.
- Wound infection: palpable induration, wound dehiscence and/or pusdrained.

If pus was drained, it was sent for pus culture and sensitivity and the corresponding organism was treated according to their antibiotic sensitivity. After collection of data it was evaluated.Both groups were compared and the statistical significance was calculated using paired t test. IBM SPSS software version 21 was used for data analysis. P value<0.05 was considered statistically significant.

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

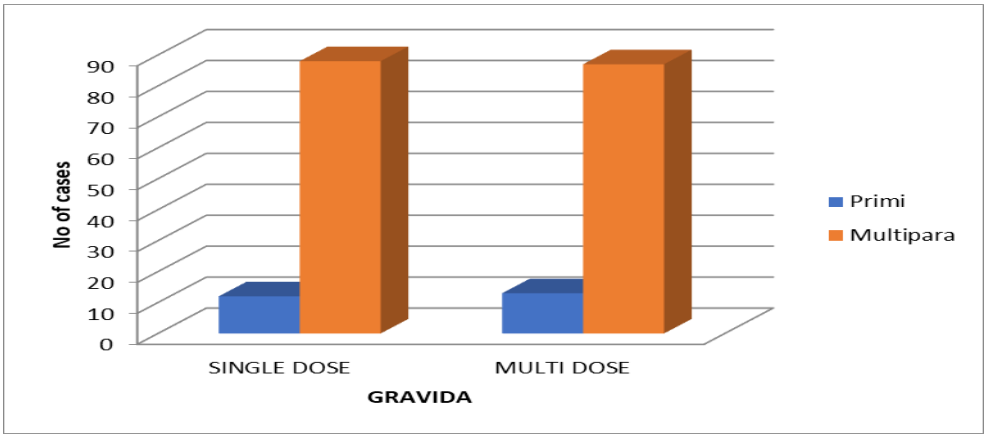
3.RESULTS

TABLE 1- MATERNAL AGE WISE DISTRIBUTION

AGE (YEARS)	SINGLE DOSE	PERCENTAGE	MULTI DOSE	PERCENTAGE
Up to 20 Years	6	6	7	7
21 – 25 Years	41	41	40	40
26 – 30 Years	38	38	37	37
31 – 35 Years	11	11	11	11
> 35 Years	4	4	5	5
Total	**100**	**100**	**100**	**100**

In group I, i.e. the single dose group, 6% were from the age group up to 20 years, 41% were from the age group 21 - 25 years & 38 % were from the age group 26 - 30 years, 11% were from the age group 31 - 35 years and 4% were above 35 years.In group II, the multi dose group, 7% were from the age group up to 20 years, 40% were from the age group 21 - 25 years & 37% were from the age group 26 - 30 years, 11% were from the age group 31 - 35 years and 5% were above 35 years.

FIGURE 1 - BAR DIAGRAM SHOWING PARITY DISTRIBUTION



Among the total cases, 12 % of single dose group hadprimi and 88% had multipara and the same in the multi dose group were 13% and 87 % respectively. It is significant from the

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

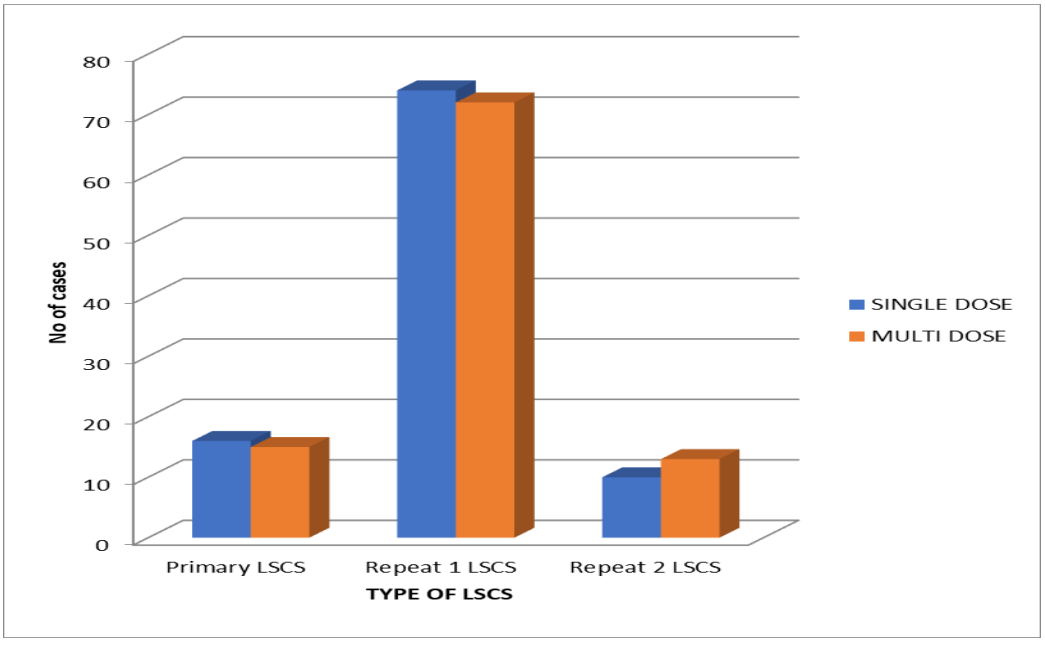
above table that in both groups the majority were with multipara gravida.

TABLE 2 – TYPE OF SURGERY DISTRIBUTION

TYPE OF SURGERY	SINGLE DOSE	PERCENTAGE	MULTI DOSE	PERCENTAGE
Primary LSCS	16	16	15	15
Repeat LSCS	84	84	85	85
Total	**100**	**100**	**100**	**100**

Among the total cases, in both the groups majority of surgery were repeat LSCS with 84% in group I and 85 % in group II. Least percentage of surgery in both the groups is the primary CS done in multiparous patients with 4% & 2% in group I & II respectively. CS done in primiparous women in group I & II is 12 % & 13% respectively.

FIGURE 2- BAR DIAGRAM SHOWING TYPE OF LSCS



Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

TABLE 3–DISTRIBUTION OF INDICATIONS

INDICATIONS	SINGLE DOSE	PERCENTAGE	MULTI DOSE	PERCENTAGE
BOH	1	1	2	2
Transverse Lie	3	3	1	1
Breech	8	8	6	6
CPD Major	3	3	3	3
Severe Oligo	2	2	4	4
Previous LSCS with CPD	73	73	71	71
Previous 2 LSCS	10	10	13	13
Total	**100**	**100**	**100**	**100**

In 200 subjects who were enrolled in the study, the most common indication for abdominal delivery was previous LSCS.In group II, where 72 previous LSCS patients was operated 71 has Previous LSCS with CPD as indication and the remaining one was operated on because of severe oligohydramnios.

FIGURE 3- BAR DIAGRAM SHOWING DURATION OFSURGERY

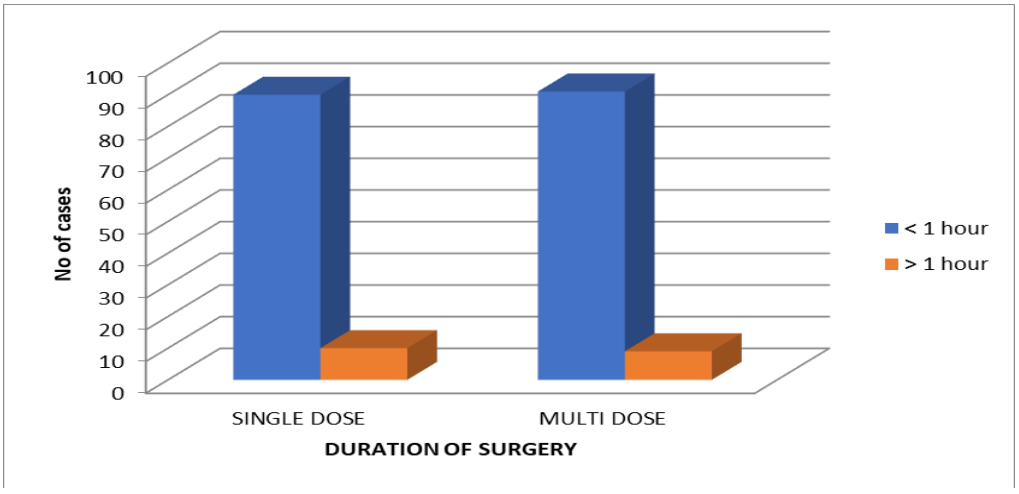


TABLE 4 – PURULENT WOUND DISCHARGE DISTRIBUTION

PURULENT DISCHARGE	SINGLE DOSE	%	MULTI DOSE	%	p value

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

Yes	3	3	2	2	0.745
No	97	97	98	98	
Total	**100**	**100**	**100**	**100**	

Among the total cases, 3 % had Purulent Discharge in the single dose group and the same was 2 % in the multi dose group. the single dose group and 1 % of subjects had abnormal vaginal discharge in multiple dose group.

.FIGURE4- BAR DIAGRAM SHOWING PATIENTS HAVING ABNORMAL VAGINALDISCHARGE

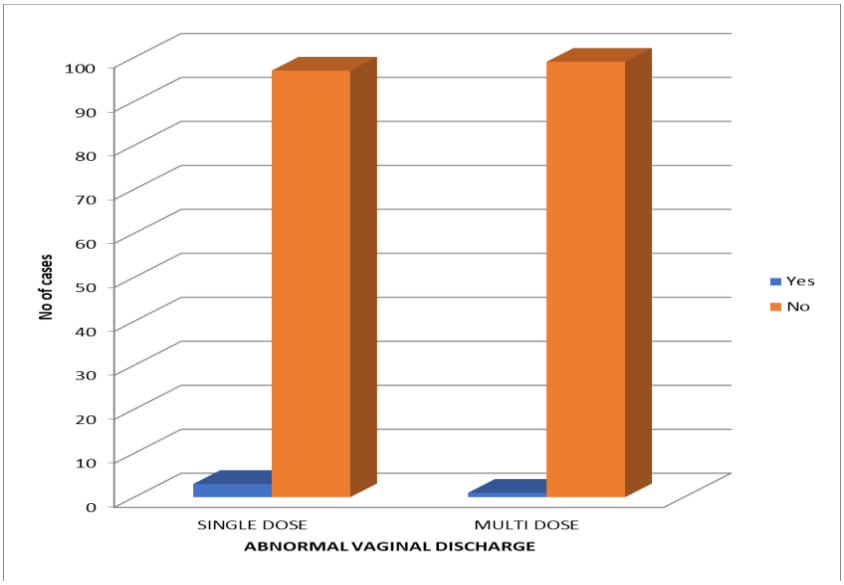


TABLE 5 – UTI DISTRIBUTION

UTI	**SINGLE DOSE**	**%**	**MULTI DOSE**	**%**	**p value**
Yes	6	6	5	5	0.741
No	94	94	95	95	
Total	**100**	**100**	**100**	**100**	

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

Among the total cases 6 % had UTI Distribution in the single dose group and the same was 5 % in the multi dose group.There was no statistical significance between the groups with respect to Hospital Stay Duration. (p value ≥ 0.05)

4.DISCUSSION

Reduction of the infection and thereby to reduce morbidity and mortality is the primary aim of prophylactic antibiotics. Perioperative administration of antibiotic while giving prophylaxis for caesarean section is necessary to ensure a high plasma concentration of antibiotic during the operation. Various recent studies in obstetric cases proved that there is a definite role of prophylactic antibiotics.In the present study 200 subjects who were enrolled and divided into study and control groups. Statistical analysis of different variables confirmed comparable groups of total number of patients. All patients in the study group received antibiotic prophylaxis half hour before surgery and those in multiple dose regimen received additional doses postoperatively and the post op outcomes were compared.10

There was no difference in the duration and amount of antibiotic used with regard to infectious morbidity. There was no statistically significant difference in outcomes whether short course or the long course of antibiotic were used.Classen et al have shown the importance of the timing of antibiotic administration in preventing postoperative infection 11,12. Small and Gyte et al in their Cochrane review concluded there is no difference regarding the time of antibiotic prophylaxis administered in regard to before cord clamp or after cord clampIn this study, a total of six patients developed febrile morbidity in group I and in group II, five patients were found to have febrile morbidity. Temperature of these patients were more than 38 degrees after 24 hours post the elective caesarean section and on average lasted for 3 to 5 days. Patients had associated abdominal wound infections, wound swab was taken and sent for pus culture and sensitivity. 13 Appropriate antibiotics were changed accordingly.

In a study conducted by Zeel Shah et ain 2014 showed results comparable to the present study while comparing febrile morbidity (P value is 0.1139).Statistically significant difference was not demonstrated in any postoperative complications in the above mentioned study mean while the study showed that the average cost between both study groups has a statistically significant difference.In group 1 the three patients who developed purulent discharge on postoperative day 5 and day 6. Injection cefotaxime 1 g IV BD was started empirically and wound swab sent for pus culture and sensitivity. 14 In patients with group I, E. Coli growth was noted in one, Staph aureus in one patient and yet another had Klebsiella growth. All the

Annals of R.S.C.B., ISSN:1583-6258, Vol. 25, Issue 3, 2021, Pages. 3838 - 3849
Received 16 February 2021; Accepted 08 March 2021.

organisms were sensitive to injection cefotaxime except for the klebsiella which showed resistance to cefotaxime. Injection Cefotaxime1 g IV BD was continued for 5 days. But Klebsiella showed sensitivity to piperacillin- tazobactam combination and meropenem, with intermediate sensitivity to ciprofloxacin. In the present study, incidence of UTI was found to be 6% & 5 % in group I & II respectively. The difference was not statistically significant. In a study conducted by J Shetty et al also showed similar findings50.In all these cases were UTI was detected, urine culture and sensitivity were done and antibiotics were given according to the sensitivity.15,16

In this study we inferred that single dose antibiotic prophylaxis is as effective as the multiple dose antibiotic prophylaxis when postoperative complications are concerned. But it might be better if the average cost of antibiotics is taken into consideration.17 There will be a statistically significant difference in cost of antibiotics in both groups, which is not taken into consideration in our present study. Moreover, the shorter course of antibiotics will reduce the risk of emergence of drug resistant strain of bacteria, which is a curse of this present time where antibiotic usage is rampant. Restriction of additional doses of antibiotics only to high risk cases will spare the vast majority of patients from unnecessary drug administration.18

5.CONCLUSION

In this era of rising antibiotic resistance, lesser usage of antibiotics has become the need of the hour and this study has given positive reinforcement towards the same direction. It is concluded from this study that the single dose prophylactic antibiotic is equally efficacious as multiple dose prophylaxis in elective uncomplicated caesarean section. There was no statistically significant difference noted between the two groups when compared in terms of febrile morbidity, wound induration, serous wound discharge, purulent wound discharge, wound gaping, uterine involution, UTI or abnormal vaginal discharge.

As an added advantage, the single-dose is more cost effective than the multi-dose prophylaxis as the amount and duration of antibiotic used is very less. It reduces the financial burden faced by the patients as well as the government for providing the antibiotics. Also, the single-dose antibiotic prophylaxis is convenient not only for the patient but for the health personnel as well because of lesser number of intravenous administrations.It has the additional advantage of sparing the vast majority of patients from unnecessary drug exposure, as there is a restriction of additional doses of antibiotics only for the high-risk cases.Hence together let us take a step forward to reduce the unwarranted usage of antibiotics and promote the use of single-dose antibiotic prophylaxis, in uncomplicated elective LSCS, as it is safe, effective, convenient,

economic and judicious way of using antibiotics.

Funding: No funding sources

Ethical approval: The study was approved by theInstitutional Ethics Committee

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGMENTS

The encouragement and support from Bharath University, Chennai, is gratefully acknowledged. For provided the laboratory facilities to carry out the research work.

BIBLIOGRAPHY

1. Gibbs RS. Clinical risk factors for puerperal infection. ObstetGynecol1980;55(5Suppl):178s–84s.
2. J.S.Bagrateeet al a randomised control trial of antibiotic prophylaxis in elective caesarean delivery BJOG 2001,108:143-148
3. Owen J, Andrews WW. Woundcomplicationsafter caesarean sections. Clin ObstetGynecol1994;37:842–55.
4. ACOG practice bulletin no.199:Useof prophylactic antibiotics in Labor and Delivery: Obstetrics and Gynaecology: September 2018-Volume 132-Issue 3-pe103- e119;
5. Robson MS. Can we reduce the caesarean section rate? Best PractRes Clin ObstetGynaecol 2001:15:179-94
6. Laura Hopkins, Fiona M SmaillAntibiotic prophylaxis regimens and drugs for caesareansectionCochraneDatabase of Systematic Reviews,1999. DOI: https://doi.org/ 10.1002/14651858.CD001136.
7. Protocol for surgical site infection surveillance with a focus on settings with limited resources. Geneva: World Health Organisation,2018. Licence: CC BY-NC-SA 3.0 IGO. Page- 12
8. SmaillFM, GrivellR. Antibiotic prophylaxis versus no prophylaxis for preventing infection after caesarean section. Cochrane Database of Systematic Reviews 2014, Issue 10. Art. No.: CD007482. DOI: 10.1002/14651858. (Systematic Review)
9. BolligC, NothackerM, LehaneC, MotschallE, Lang B, MeerpohlJJ, et al. Prophylactic antibiotics before cord clamping in cesarean delivery: a systematic review.ActaObstetGynecolScand2018;97:521–535. (Systematic Review)
10. TeLindesoperative gynaecology, Ninth edition, Wound healing, suture material and surgical instrumentation, Pg233-236
11. J.M. Roex, J.I. Puyenbroek, A.C. van Loenenand N.F.T. Art Single- versus three-dose cefoxitin prophylaxis in caesarean section: a randomized clinical trial Eur. J. Obstet. Gynecol. Reprod. Bioi., 25 (1987)293-29.
12. Robinson HE, O'Connell CM, Joseph KS, McLeod NL. Maternal outcomes in pregnancies complicated by obesity. Obstet

Gynecol.2005;106:1357-1364.

13. Teodorico: The Surgery of Theodoric, ca. A.D. 1267 (translated by Campbell E, Colton J). New York: Appleton- Century- Crofts,1955.
14. Alexander JW: The contributions of infection control to a century of surgical progress. Ann Surg 201:423–428,1985.
15. Meade RH: An Introduction to the History of GeneralSurgery. Philadelphia: WB Saunders, 1968, pp29–37.
16. Noel GJ. Clinical profile of ceftobiprole, a novel beta- lactam antibiotic. Clin Microbiol Infect 2007; 13 Suppl2:25.
17. Goodman and Gilman's, The pharmacological basis of therapeutics,12thEdition, chapter 53,page1497
18. J Shetty, S. Rajshekhar, A Kamath. Short termantibiotics for emergency caesarean delivery: is there a difference? The internet journal of gynaecologyand obstetrics 2009 volume 1DOI:10:10.5580/207e.