

## CALCULATING SURGICAL SITE INFECTION RATES IN PEDIATRIC ORCHIDOPEXY WITHOUT PROPHYLACTIC ANTIBIOTICS

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### ABSTRACT:

**Introduction:** Undescended testes (UDT) is the most common congenital anomaly of the urogenital system in male newborns. Testicular descent into scrotum is necessary for normal spermatogenesis. The scrotal temperature is 2-7 degrees below body temperature. UDT are prone to impaired spermatogenesis, Surgical site infection (SSI) is a leading cause of postoperative morbidity and mortality. It is the third most common cause of hospital acquired infections. However injudicious use of antibiotics is responsible for increased costs, unwanted drug side effects like Clostridium difficile infection as well as the emergence of resistant strains and multidrug resistant infections.

**Objective:** To determine the frequency of surgical site infection in pediatric patients undergoing orchidopexy without the administration of prophylactic antibiotics.

**Study design:** Descriptive Study

**Setting:** Department of pediatrics, Lady Reading Hospital Peshawar.

**Duration of study:** From 08-July-2020 to 08-January-2021.

**Materials and Methods:** A total of 126 cases of undescended testis were selected in a consecutive manner OPD and subjected to orchidopexy. Follow up was done to detect the presence or absence of SSI.

**Results:** The mean age of the sample was 12.9+6.9 months. Mean weight of the included children was

12.8 4.9 kg and mean height was 73.1+ 13.5 cm. 50.8% Presented with right side undescended testis and 57.1% were in ASA class Mean operative time for orchidopexy was 44.4 10.3 minutes. SSI was recorded in 31 (24.6%) of children.

**Conclusion:** Surgical site infection (SSI) is a significant concern in pediatric patients undergoing orchidopexy for unilateral undescended testis. Further research is needed to identify the risk factors associated with SSI in children and develop effective preventive strategies. The use of prophylactic antibiotics should be carefully considered, considering the potential risks and benefits. Addressing SSI in this population is crucial for improving patient outcomes and reducing the burden of complications.

### INTRODUCTION:

Undescended testes (UDT) is the most common congenital anomaly of the urogenital system in male newborns. It is present in approximately 3% term and 30% preterm infants all over the world. Spontaneous descent occurs in up to 70% patients with the first 3 months of life; however, after 6 months a surgical intervention is required.<sup>1</sup> The risk factors for UDT include prematurity,

intrauterine growth retardation (IUGR), perinatal asphyxia, cesarean delivery, and toxemia of pregnancy to name a few.<sup>2</sup> The Testicular descent into scrotum is necessary for normal spermatogenesis. The scrotal temperature is 2-7 degrees below body temperature. UDT are prone to impaired spermatogenesis and increased risk of male infertility due to thermal injury because of exposure of testes to normal body temperature. It is also associated with an increased risk of testicular tumors in adult life.<sup>2,3</sup> According to the guidelines of the American Academy of Pediatrics, the European Association of Urologists, and the Nordic consensus, orchidopexy should be performed around the age of 1 year to prevent long term complications.<sup>1,4</sup> Surgical site infections (SSIs) are a significant contributor to postoperative morbidity and mortality. They rank as the third most prevalent type of hospital-acquired infections, comprising more than one-fifth of all healthcare-associated infections.<sup>5</sup> The incidence of in pediatric age group ranges from 2.5% to 20%. SSIs increase the financial burden on the patients and the healthcare setups. Antibiotic prophylaxis is therefore administered to prevent SSIs.<sup>6</sup> The indiscriminate use of antibiotics is associated with various negative consequences, including increased costs, unwanted drug side effects like Clostridium difficile infection, and the emergence of resistant strains and multidrug-resistant infections. In recent years, there has been a growing interest in exploring the potential clinical advantages of performing clean pediatric surgeries without administering antibiotic prophylaxis.<sup>7</sup>

A study by Vaze et al published in 2014 compared the frequency of SSI in patients undergoing

#### **MATERIALS AND METHODS:**

**Study Design:** Descriptive Study.

**Study Setting:** Department of Pediatric Surgery, Lady Reading Hospital, Peshawar.

inguinal herniotomy and orchidopexy between cases (group without the administration of prophylactic antibiotics to controls (group receiving prophylactic antibiotics) and found the frequency of SSI was 3.73% in cases versus 2.22% in controls which was statistically non-significant ( $p=0.703$ ).<sup>8</sup> Kekre et al in 2018 reported that the out 24 (4.17%) patients undergoing orchidopexy without antibiotic prophylaxis suffered from SSIs.<sup>9</sup> Another study by Rensing et al in 2018 studied 47690 patients undergoing orchidopexy without antibiotic prophylaxis and reported that surgical antibiotic prophylaxis was not associated with a decreased risk of SSI. The study reported that the frequency of SSI in patients undergoing orchidopexy occurring within 30 days of the procedure who did not receive antibiotic prophylaxis was less than 0.1%. The comparison of patients receiving antibiotic prophylaxis and those without antibiotic prophylaxis also revealed a statistically insignificant correlation ( $p=0.51$ ).<sup>10</sup>

The rationale of this study is that there is paucity of data in the Pakistani population with no previous study on determination of frequency of SSI in pediatric patients without the use of prophylactic antibiotics. Injudicious use of antibiotics is one of the major dilemmas of the present era. Therefore, the findings of this study will help to reduce the cost of antibiotics, adverse side effects associated with antibiotics use and will also help to reduce development of resistant strains. The main objective of this study is to determine the frequency of surgical site infection in pediatric patients undergoing orchidopexy without the administration of prophylactic antibiotics.

**Duration of Study:** 6 months after approval of synopsis. From 08-07-2020 to 08-01-2021.

**Sample Size:** The sample size has been calculated by WHO sample size calculator as follows,

1. Confidence level (1-  $\alpha$ )  
= 95%.
2. Absolute precision required (d)  
= 3.5
3. Anticipated population proportion  
(frequency of SSI) = 3.5.
4. Sample size (n)  
= 126 patients

1. Undescended testes with testes not palpable in the inguinal canal or the base of the scrotum.
2. Patients taking antibiotics for any infection in the body.
3. Patients who had a history of use of antibiotics in the past one week.
4. Patients already having infection at the surgical site before the operation.
5. Patients having concomitant pathologies of the scrotum like inguinal hernia.
6. Patients not giving consent to be enrolled in the study

The above-mentioned conditions also acted as confounders, hence excluded from the study.

After approval from hospital ethical review committee Lady Reading Hospital, Peshawar, a written informed consent was taken from parents/guardians of all patients included in the study. After recording of demographic details, clinical examination was performed, Patients with unilateral undescended testicle lying in the base of the scrotum or palpable in the inguinal canal were included in the study. Routine laboratory investigations were carried out and fitness for general anesthesia was obtained. All surgeries were carried out under general anesthesia and no prophylactic antibiotics were given at the time of induction of anesthesia or after orchidopexy. Surgery time was measured in minutes from time of incision till the application of last stitch at the end of the surgery. Post-operatively all patients were discharged in the

Sampling Technique: Non-Probability  
Consecutive Sampling

Inclusion Criteria:

1. Age between 6 months to 2 years.
2. Patients having unilateral undescended testes with testes palpable in the inguinal canal or at the base of the scrotum
3. ASA Class I and II

Exclusion Criteria:

evening of the day of surgery, and they would be followed in pediatric surgery OPD on 7<sup>th</sup>, 14<sup>th</sup> and 28<sup>th</sup> post-operative days.

All patients were followed for surgical site infection. Data for each patient was recorded on predesigned patient's proforma. Follow up was ensured by taking contact numbers of the patients. Throughout the study, all patients were treated with utmost respect and their comfort was prioritized. The exclusion criteria were meticulously adhered to manage confounding factors and minimize bias in the study.

Data analysis was conducted using SPSS version 25.0. Quantitative variables such as age, height, weight, and operation time were assessed by calculating the mean and standard deviation. Categorical variables, including surgical site infection, ASA class, and laterality (side involved), were analyzed by determining frequency and percentages. To control for effect modifiers such as age, height, weight, ASA class, laterality, and operative time, stratification was performed. The frequency of SSI was compared between stratified groups using the chi-square test, with a significance level set at  $p < 0.05$ .

#### RESULTS:

The study was conducted on 126 children presenting with unilateral undescended testis and subjected to orchidopexy. The Mean age of the sample was  $12.9 \pm 6.9$  months. The mean weight of the included children was  $12.8 \pm 4.9$  kg and mean height was  $73.1 \pm 13.5$  cm. 50.8% presented with right side undescended testis and 57.1% were in ASA class I. Mean operative time for

orchidopexy was  $44.4 \pm 10.3$  minutes. SSI was recorded in 31 (24.6%) of children. (Table 1, Figure 1)

*Table 1*

Variables	Frequency	Percent
<b>Age Groups</b>		
2-12 months	57	45.2%
>12-24 months	69	54.8%
<b>Weight</b>		
5-10 Kgs	54	42.9%
>10-15kgs	33	26.2%
>15-20Kgs	39	31%
<b>Height</b>		
45-60cm	32	35.4%
>60-75cm	43	34.1%
>75-95cm	51	40.5%
<b>Laterality</b>		
Right	64	50.8%
Left	62	49.2%
<b>ASA Class</b>		
ASA i	72	57.1%
ASA ii	54	42.9%
<b>Operative Time</b>		
30-45 mins	82	65.1%
>49-69 min	44	34.9%
<b>Surgical Site Infection</b>		
Yes	31	24.6%
No	95	75.4%

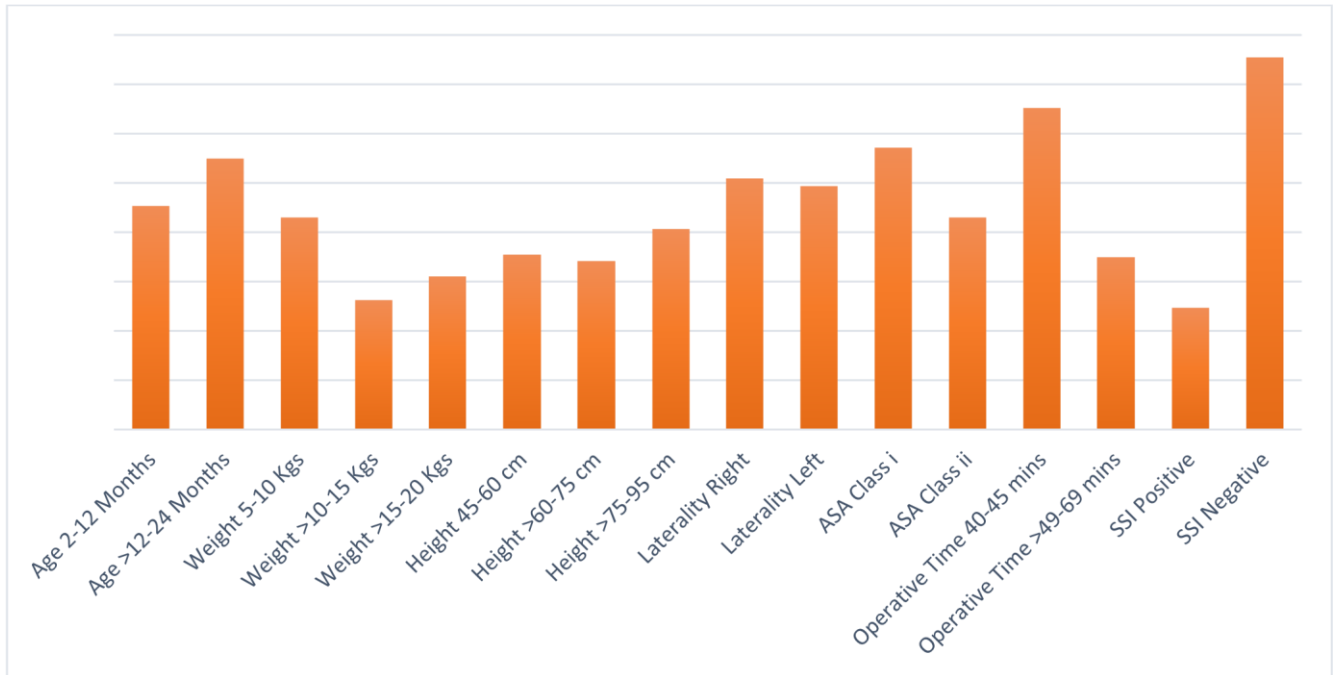


Figure 1

SSI was stratified individually with age, weight, height, laterality, ASA class and operative time and P values were calculated by using Chi-square test given in Table 2.

Table 2

Variables	SSI Positive	SSI Negative	P Value
<b>Height OF Child</b>			
<b>45-60 cm</b>	7	25	0.917
	21.9%	78.1%	
<b>&gt;60-75 cm</b>	11	32	
	25.6%	74.4%	
<b>&gt;75-95 cm</b>	13	95	
	25.5%	74.5%	
<b>Total</b>	31	95	
	24.6%	75.4%	
<b>Laterality</b>			
<b>Right</b>	14	50	0.470
	21.9%	78.1%	
<b>Left</b>	17	45	
	27.4%	72.6%	
<b>Total</b>	31	95	

	24.6%	75.4%	
<b>ASA Class</b>			
<b>ASA i</b>	19	53	0.591
	26.4%	73.6%	
<b>ASA ii</b>	12	42	
	22.2%	77.8%	
<b>Total</b>	31	95	
	24.6%	75.4%	
<b>Operative Time</b>			
<b>30-40 minutes</b>	21	61	0.720
	25.6%	74.4%	
<b>&gt;45-60 minutes</b>	10	34	
	22.7%	77.3%	
<b>Total</b>	31	95	
	24.6%	75.4%	

**Discussion:**

The occurrence of Surgical Site Infection (SSI) is a significant factor in assessing surgical results, especially in pediatric surgery. Prolonged hospital stays often result from wound infections and complications related to wounds. Existing research indicates a wide range in the incidence of postoperative wound infections in children, ranging from 1.6% to 18.7%, and even higher rates of 27% for contaminated surgeries and 30%-40% for dirty infected surgeries.<sup>11-18</sup> Incidence of SSI depends on the class of the wound.<sup>13</sup> Wound infection is more likely to occur in emergency surgeries and surgeries that exceed a duration of 1 hour. Additionally, newborn surgeries and surgeries involving the use of open drains carry a higher risk for the development of wound infections.<sup>18,16</sup> However, the current literature does not provide a specific analysis of the occurrence of wound infections based on complications related to the surgery itself.<sup>15,19</sup> In our study SSI were reported towards a higher side (24.6%), which is consistent with literature

data reporting 10-40.7%.<sup>15,18,21,23</sup> On the contrary, van Griethuysen et al. and Horwitz et al. have presented contrasting findings, stating that the infection rate for dirty operations is actually lower compared to contaminated operations.<sup>20,24</sup> While these studies did not identify a specific reason for this observation, Bhattacharyya et al. provided an explanation for the higher infection rate in contaminated operations. They noted that one-third of surgical wounds, particularly in the case of dirty-infected surgeries, were not primarily closed, which could contribute to the increased risk of infection.<sup>21</sup> Cruse's study found a significant increase in hospital stays, averaging 12.6 days, in the presence of SSI.<sup>19</sup> While most studies indicate a longer hospital stay in cases of Surgical Site Infection (SSI), the specific reasons for this prolonged duration are not specified.<sup>23,25</sup> Numerous studies have established a correlation between longer surgery durations and an increased rate of Surgical Site Infections (SSIs).<sup>11,13,18,22</sup> Cruse et al. found a direct link

between longer operation durations and a nearly twofold increase in the rate of SSI per hour.<sup>19</sup> Opinions regarding the use of antibiotics are inconsistent. However, Porrás-Hernández et al. and Fletcher et al. demonstrated that antibiotic prophylaxis, while marginally significant, acted as a protective factor against Surgical Site Infections (SSI).<sup>15,22</sup> Uludag et al. emphasized that even with the implementation of antibiotic prophylaxis, the rate of wound infection for dirty-infected surgeries remained at 30%.<sup>18</sup> In the present study, the rate of wound infection was higher even after antibiotics were used prophylactically.

A prior study revealed that surgical antibiotic prophylaxis (SAP) did not yield any advantages in pediatric circumcisions and, in fact, carried a clear heightened risk of adverse events.<sup>26</sup> Additional studies have similarly proposed the safety of excluding surgical antibiotic prophylaxis (SAP) in pediatric hernia repair and orchiopexy. However, due to the relatively small patient cohorts and the infrequent occurrence of postoperative surgical site issues, a large patient cohort is necessary to establish whether a definitive benefit or detriment exists.<sup>27</sup> Evidence in the adult literature supports the notion that surgical antibiotic prophylaxis (SAP) does not reduce the risk in specific clean procedures, such as microsurgical varicocelectomy, adrenalectomy, partial nephrectomy, and nephrectomy.<sup>28,29</sup> Some studies suggest that topical antibiotic prophylaxis may be advantageous in adult microsurgical varicocelectomies, which share similarities with pediatric orchiopexy.<sup>30</sup>

Previous studies have highlighted the absence of evidence-based guidelines for surgical antibiotic prophylaxis (SAP) in common procedures, resulting in substantial variability in SAP usage. This pattern is observed in other clean and clean-contaminated pediatric procedures, including circumcision, inguinal hernia repair, hydrocele

repair, laparoscopic varicocelectomy, hypospadias repair, endoscopic urological procedures, and spinal procedures.<sup>31</sup>

According to the most recent American Urological Association (AUA) Best Practice Policy Statement, surgical antibiotic prophylaxis (SAP) is recommended for clean-contaminated, adult urologic procedures. However, SAP is not recommended for clean procedures unless specific risk factors are present.<sup>32</sup> A multisociety guideline also advises against the use of surgical antibiotic prophylaxis (SAP) for clean pediatric procedures.<sup>33</sup> European guidelines have put forward similar recommendations, emphasizing the need for renewed attention to antibiotic stewardship, particularly in pediatric treatment, due to increasing concerns about drug-resistant bacterial strains.<sup>34,35</sup>

The strength of this study lies in its adequate sample size of 126 pediatric patients, which was determined using a reliable sample size calculator. This ensures that there is sufficient data for analysis and enhances the generalizability of the findings to a broader population. Additionally, the study included a follow-up period of 28 days, with patients being evaluated on the 7th, 14th, and 28th postoperative days. This extended follow-up allows for the detection of surgical site infections over a reasonable duration, providing a comprehensive assessment of the outcomes.

However, there are certain limitations to consider. Firstly, the study was conducted in a single center, which may limit the generalizability of the results to other healthcare settings. Variations in surgical practices, patient characteristics, and healthcare resources among different centers may influence the frequency of surgical site infections. Furthermore, the study utilized a non-probability consecutive sampling technique, introducing the possibility of selection bias. This could affect the representativeness of the sample and potentially impact the validity of the results. A randomized



controlled trial design would have minimized selection bias and provided stronger evidence.

**Conclusion:**

This study highlights the significant occurrence of surgical site infections (SSI) in pediatric patients undergoing orchidopexy for unilateral undescended testis. The findings emphasize the importance of addressing this serious complication and call for further research to identify the risk factors associated with SSI in children. Understanding these factors will contribute to the development of effective preventive strategies and future research directions. It is worth noting that the injudicious use of antibiotics, although common in preventing SSIs, can lead to increased costs, adverse drug effects, and the emergence of antibiotic-resistant strains. Therefore, it becomes essential to strike a balance between the use of prophylactic antibiotics and minimizing the associated risks. Future studies should focus on optimizing the administration of antibiotics, considering the specific needs and characteristics of pediatric patients. Overall, this study sheds light on the challenges posed by surgical site infections in pediatric orchidopexy procedures and underscores the importance of further investigation to improve patient outcomes and reduce the burden of SSI in this population.

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