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"A Clinical Study of Mc. Indoe's Vaginoplasty for Vaginal Agenesis ''

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Abstract:
Background: *Vaginal agenesis is a very rare malformation which has an estimated incidence of 1 in 4000-5000 live female child births.This is the most traumatic congenital anomaly. It can occur as an isolated development defect or may be associated with other anomalies mostly Mayer RokitanskyKuster Hauser Syndrome. Vaginal agenesis is diagnosed usually at adolescence due to amenorrhea and coital problems. Females with this disorder cannot bear children and enjoy sexual satisfaction, that leads an impact on functional and psychosocial impacts on women.*
Methods: *This study is a prospective, observational cohort of 8 patients who presented with vaginal agenesis to the department of plastic surgery and Gynaecology at Gandhi medical college and hospital, Secunderabad between September 2019 and September 2021.*
Results: *50% affected was in the age group 21-25years . The most common presenting complaint was primary amenorrhoea which was seen in 75% of patients.75% were unmarried. 75% patients underwent Mc. Indoe'sVaginoplasty presented with a complaint of primary amenorrhoea.25% of patients had presenting complaint of cyclical abdominal pain for which drainage of hematocolpos and Mc. Indoe'sVaginoplasty was done. The mean vaginal length is 8.5 cms*
Conclusion: *Mc.Indoevaginoplasty is a simple and effective procedure for recreation of neovagina for vaginal agenesis, create an adequate passageway for penetration and also to facilitate satisfactory sexual intercourse*
Keywords: *Mc.Indoevaginoplasty,SSG, primary amenorrhoea,Mould.*

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I. Introduction

Vaginal agenesis is a very rare malformation which has an estimated incidence of 1 in 4000-5000 live female child births .This is the most traumatic congenital anomaly. It can occur as an isolated development defect or may be associated with other anomalies mostly Mayer Rokitansky Kuster Hauser Syndrome. This syndrome is one of the common cause of primary amenorrhea. In this syndrome there is absence of uterus and upper 2/3 rd of vagina with 46xx karyotype and normal physiological growth of secondary sexual features. Its incidence is 1 in 4000 live births. Isolated congenital vaginal atresia is a rare congenital anomaly of female reproductive tract due to failure of canalization in urogenital sinus. Its incidence is 1in 5000 -6000 female births.

Menarche is the appearance of menstruation for the first time. Menstruation is the physical herald which determines physiological capacity of conception. Attaining menarche makes a girl child confident and feminine in nature . It is an occasion to celebrate in Indian families where girl gets ceremoniously blessed. At the same time not attaining menarche makes that girl and family go through a lot of psychological trauma in Indian society. Primary amenorrhea is defined as an absence of initiation of menstruation by age of 14 in the absence of secondary sexual characteristics or by the age of 16 in the presence of normal development of secondary sexual characteristics.

Vaginal agenesis is diagnosed usually at adolescence due to amenorrhea and coital problems. Females with this disorder cannot bear children and enjoy sexual satisfaction, that leads an impact on functional and psychosocial impacts on women.There are both nonsurgical and surgical methods for the treatment of vaginal agenesis. Nonsurgical options include vaginal dilatation with a dilator ,while surgical options include Vecchietti procedure ,Davydov technique ,Mc indoes technique and intestinal Vaginoplasty.

In this study MC.INDOE'S vaginoplasty procedure is used in creation of neovagina where split thickness skin graft is used to line the created neovagina. The purpose of this treatment is to create an adequate passage for penetration and to facilitate satisfactory outcome.

II. Methods

The study was conducted in the Department of Plastic and Reconstructive Surgery, Gandhi Medical College, Secunderabad from September 2019 to September 2021, A total of 8 patients were included in the study.
This is a clinical, prospective & observational study conducted over 2 years.

INCLUSION CRITERIA-
Patients with vaginal agenesis with or without hematocolpos and hematometra admitted in the Department of Plastic Surgery and Gynecology at Gandhi Hospital, during the study period.

EXCLUSION CRITERIA-
1.Testicular feminization syndrome,
2.Ambiguous genitalia,
3.Intersex and
4.Androgen insensitivity syndrome

METHOD OF COLLECTION OF DATA -
All the study subjects were admitted for vaginal agenesis in the department of plastic surgery and Gynecology over 2 years.

All routine investigations like complete blood count, Random blood sugar, Renal function tests, Serum electrolytes, Viral markers, Blood group and type, Electrocardiogram, and Chest x-ray if necessary.
Procedure requirements:

1. Pre-op bowel preparation
2. Materials [sponge, dental compound, condom, etc.]
3. Foley's catheterization
4. SSG [intermediate thickness] – in sheet
5. Meticulous sharp & blind dissection and hemostasis. [assistant's finger & Foley's bulb as a surgeon's guard for safe dissection

OPERATIVE TECHNIQUE

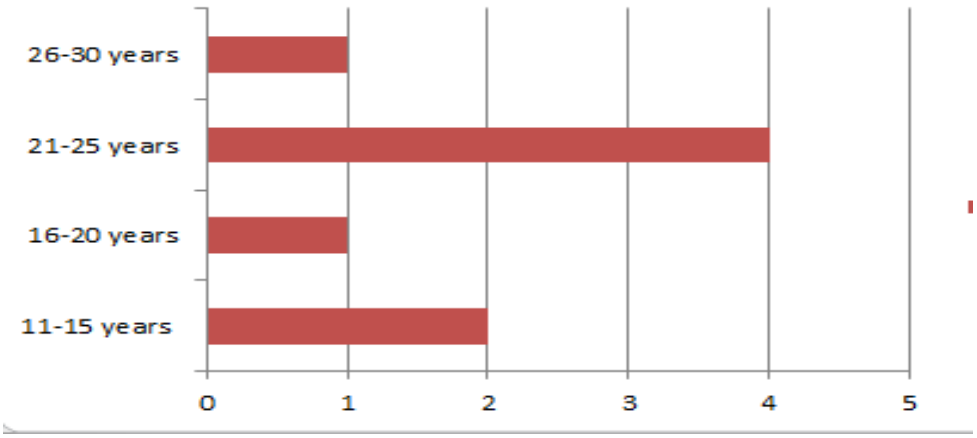
1. All patients were operated on under spinal anesthesia in the lithotomy position with urinary catheterization
2. Before starting the surgery, a first-generation cephalosporin was administered as a prophylactic antibiotic
3. The dimple in the introital area is identified. The labia are retracted & and a transverse incision is made in the perineum.
4. A vesicorectal space was created by blunt, and occasionally sharp, dissection between the urethra, bladder and the rectum.
5. The Douglas pouch represented the upper limit of dissection.
6. Meticulous hemostasis should be maintained throughout the cavity.
7. In cases of hematometra evacuation melacot's catheter was placed as a drain through the centre of the conformer for the passage of secretions.
8. A Humby's knife was used to harvest a split-thickness skin graft from the thigh
9. The SSG is placed in a sterile pan filled with saline solution after pie crusting
10. The Sponge is Shaped into the desired vaginal form.
11. The condom is slipped over the vaginal-form then the end of the condom is tied to make it air-tight.
12. The vaginal form is laid on the epidermal side of the SSG. The graft is folded over the vaginal form & sutured [care not to puncture the condom while suturing].
13. The skin graft –covered vaginal form is inserted into the cavity.
14. To hold the form in place for 5 days, the labia are sutured in the midline with interrupted sutures without tension.
15. On 5th P.O.D, after thorough inspection and irrigation. A vaginal mould made of acrylic compound is be placed.
16. Patient's got discharged between 7th -10th P.O.D.
17. Patient's education on douching, continuous mould placement and follow ups were emphasized.
18. Follow up in 1st month – weekly then monthly

III. Results

A total of 8 patients are included in the study

TABLE 1: AGE DISTRIBUTION (N=8)

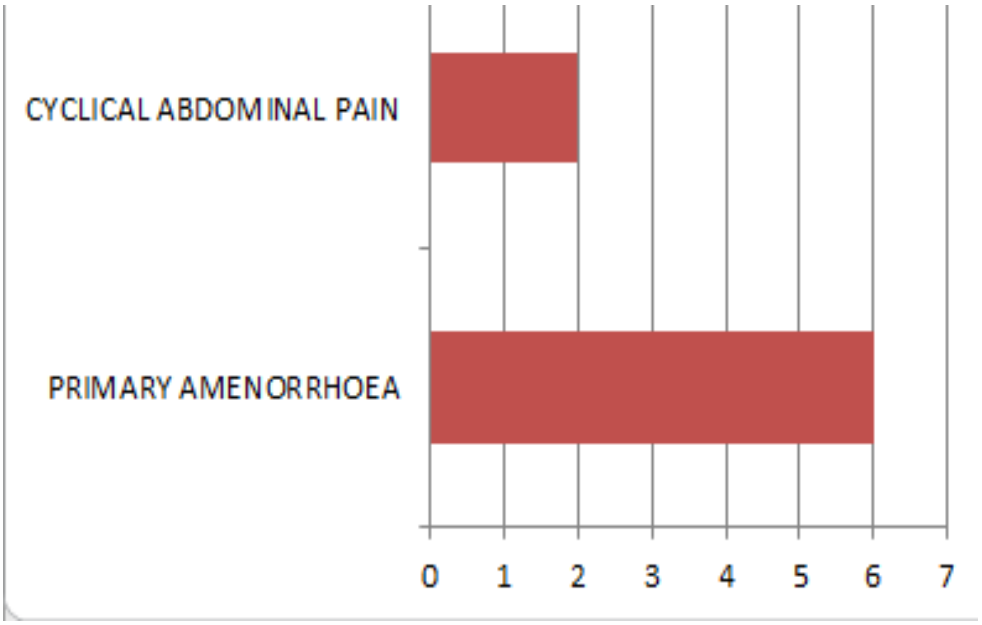
AGE(YEARS)	NO OF CASES
11-15	2(25%)
16-20	1(12.5%)
21-25	4(50%)
26-30	1(12.5%)



According to the above table (Table 1), the most common age group affected was 21-25years (50%) followed by 11-15 years (25%). The youngest patient in this study was 12 year old and the oldest patient was 27 years age. The mean age is 20.25

TABLE 2: PRESENTING COMPLAINT (N=8)

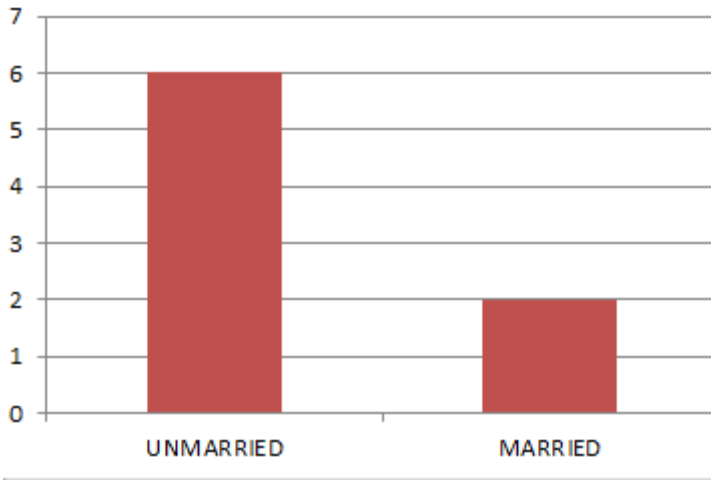
PRESENTING COMPLAINT	NO OF CASES
PRIMARY AMENORRHOEA	6(75%)
CYCLICAL ABDOMINAL PAIN	2(25%)



According to Table 2, the most common presenting complaint was primary amenorrhoea which was seen in 75% of patients. The second most common presenting complaint was cyclical abdominal pain which was seen in 25 % of patients.

TABLE 3: MARITAL STATUS(N=8)

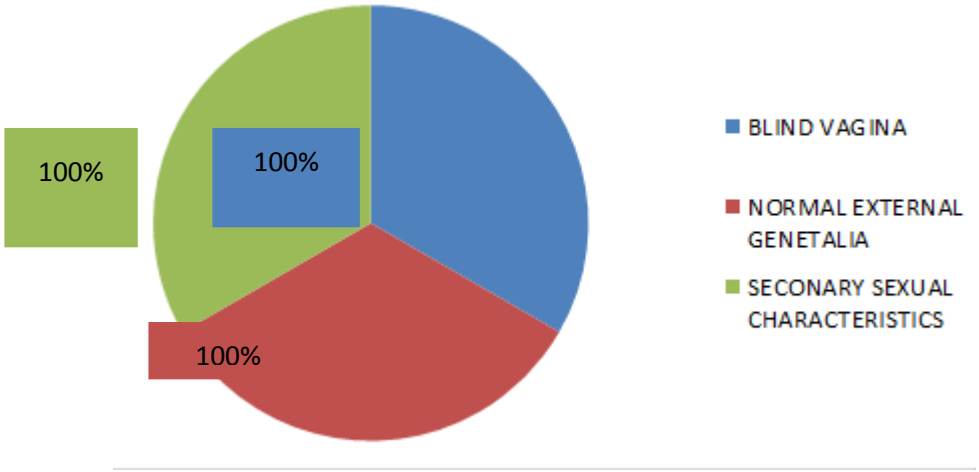
MARITAL STATUS	NO OF CASES
UNMARRIED	6(75%)
MARRIED	2(25%)



According to Table 3,Six (75%) out of eight cases were unmarried ,two (25%) were married.

TABLE 4 : GYNAECOLOGICAL EXAMINATION(N=8)

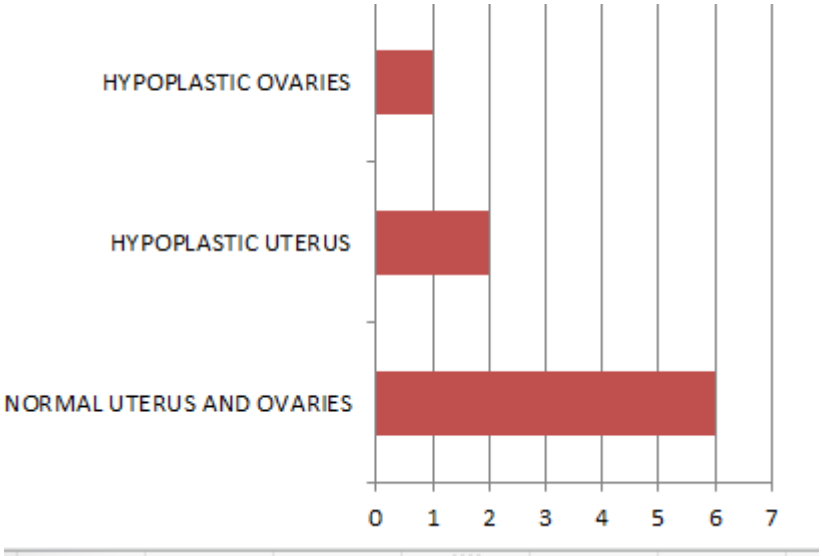
EXAMINATION	NO OF CASES
BLIND VAGINA	8(100%)
NORMAL EXTERNAL GENETALIA	8(100%)
SECONARY SEXUAL CHARACTERISTICS	8(100%)



In this study as depicted in table 4, on gynaecological examination about 100% of patients had blind vagina ,normal external genetalia and seconary sexual characteristics.

TABLE 5 : ULTRA SOUND FINDINGS(N=8)

ULTRA SOUND FINDINGS	NO OF CASES
NORMAL UTERUS AND OVARIES	6(75%)
HYPOPLASTIC UTERUS	2(25%)
HYPOPLASTIC OVARIES	1(12.5%)



According to Table 5,Among 8 patients ,75 % of the patients had normal uterus and ovaries ,25% patient had hypoplastic uterus and 12.5% patient had hypoplastic ovaries

TABLE 6: MRI FINDINGS(N=8)

MRI FINDINGS	NO OF CASES
MASSIVE HEMATOCOLPOS	2(25%)
VAGINAL ATRESIA	8(100%)
NORMAL CERVIX	8(100%)
NORMAL UTERUS AND OVARIES	6(75%)
HYPOPLASTIC UTERUS	2(25%)
HYPOPLASTIC OVARIES	1(12.5%)

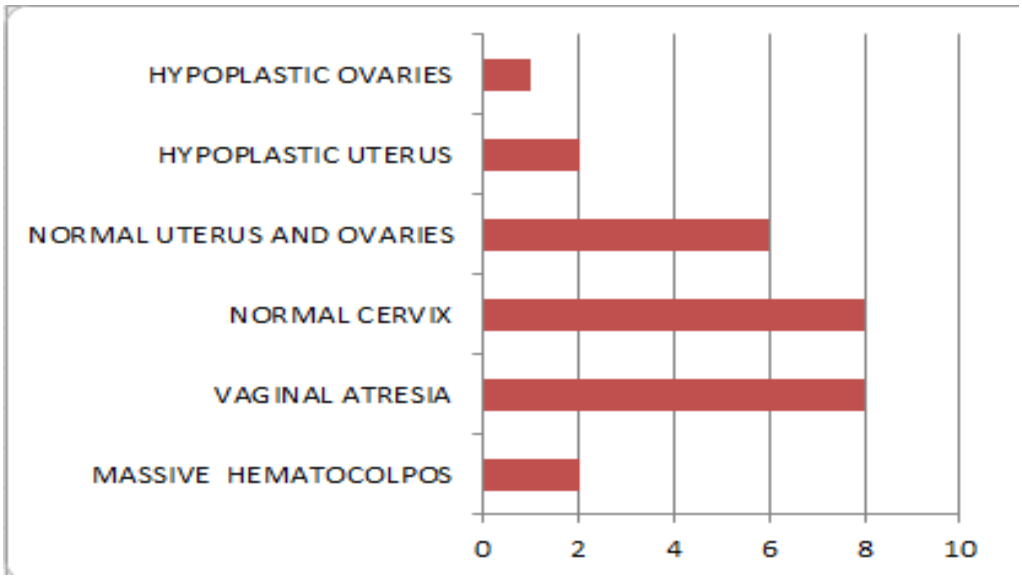
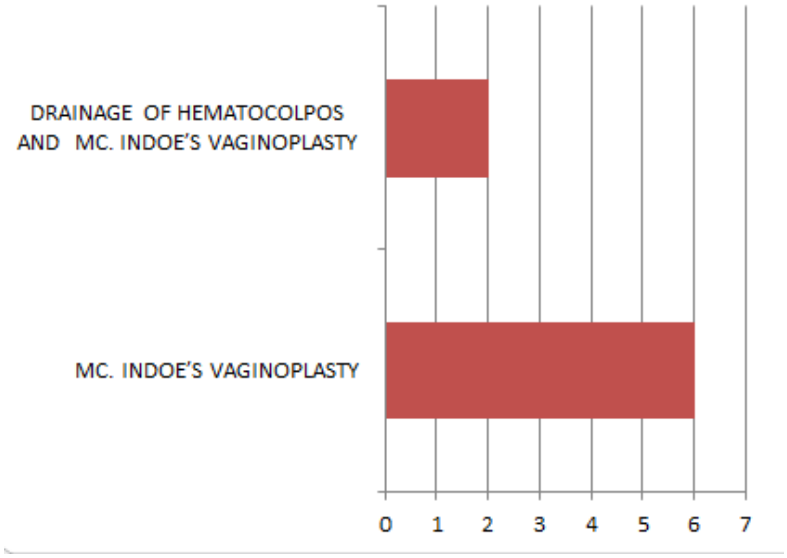


Table 6 shows ,100% of the patients had vaginal atresia with normal cervix,75% patient had normal uterus,25 % patient had hypoplastic uterus ,12.5% had hypoplastic ovaries .Among these patients 25 % of the patients had massive hematocolpos

TABLE 7: OPERATIVE PROCEDURE(N=8)

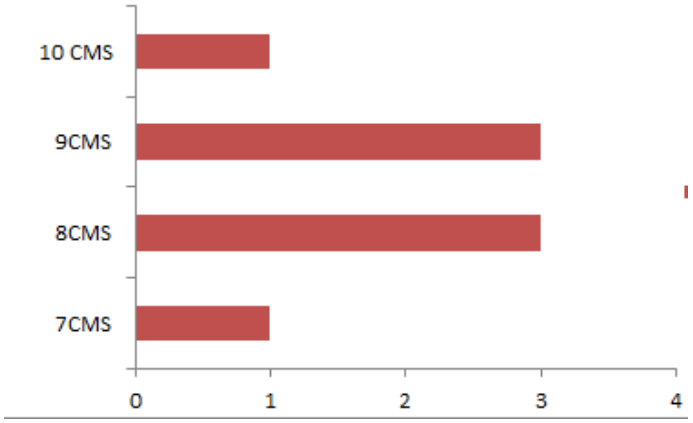
OPERATIVE PROCEDURE	NO OF CASES
MC. INDOE'S VAGINOPLASTY	6(75%)
DRAINAGE OF HEMATOCOLPOS AND MC. INDOE'S VAGINOPLASTY	2(25%)



75% patients underwent Mc. Indoe's Vaginoplasty presented with a complaint of primary amenorrhoea.25% of patients had presenting complaint of cyclical abdominal pain for which drainage of hematocolpos and Mc. Indoe's Vaginoplasty was done

TABLE 8 :LENGTH OF NEOVAGINA

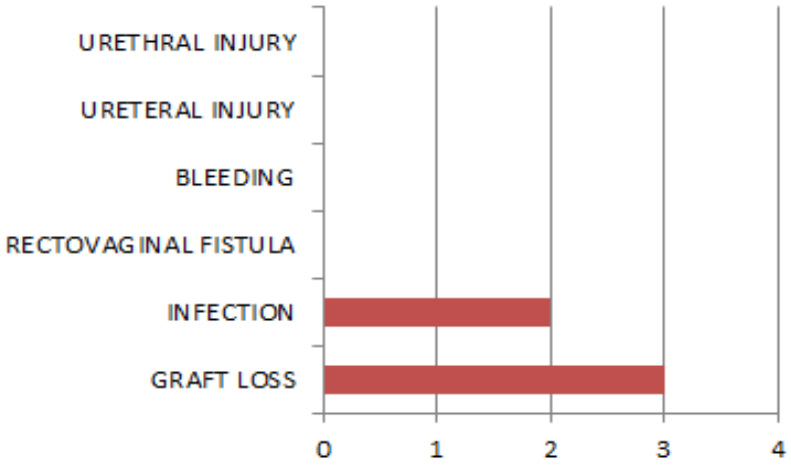
LENGTH OF NEO VAGINA IN CMS	NO OF CASES
7CMS	1(12.5%)
8CMS	3(37.5%)
9CMS	3(37.5%)
10 CMS	1(12.5%)



From the above table 8 ,12.5% patient has attained highest length of 10cms of neovagina postoperatively .12.5% patients have attained lowest length of 7 cms of neovagina postoperatively.The mean vaginal length is 8.5 cms

TABLE 9 : COMPLICATIONS

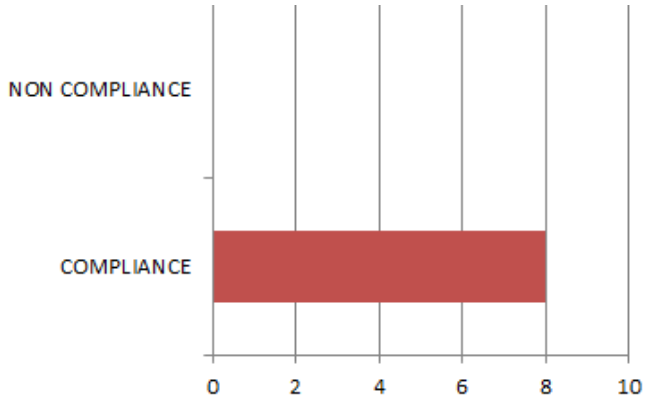
COMPLICATIONS	NO OF CASES
GRAFT LOSS	3(37.5%)
INFECTION	2(25%)
RECTOVAGINAL FISTULA	0(0%)
BLEEDING	0(0%)
URETERAL INJURY	0(0%)
URETHRAL INJURY	0(0%)



From the above table among 8 patients 37.5% of patients had graft loss and 25 % of patient had infection

TABLE 10 :COMPLIANCE WITH MOULD

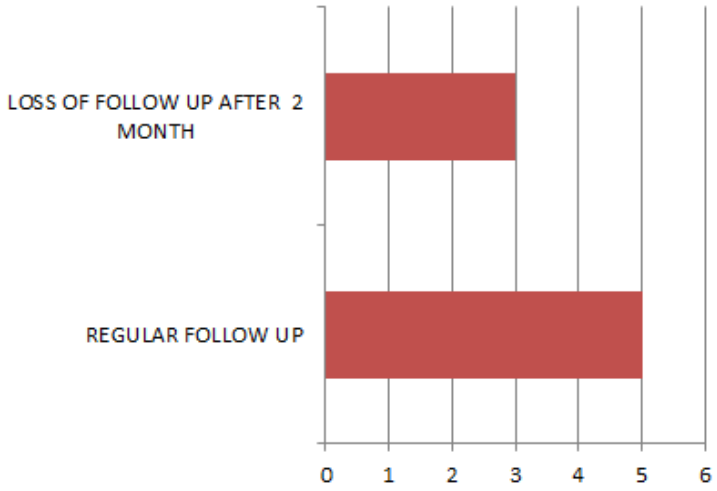
MOULD USAGE	**NO OF CASES**
COMPLIANCE	8(100%)
NON COMPLIANCE	0(0%)



From the above table 100 % of the patients used mould as per the instructions for 1 year.

TABLE 11 :POST OPERATIVE FOLLOW UP

POST OPERATIVE FOLLOW UP	NO OF CASES
REGULAR FOLLOW UP	5(62.5%)
LOSS OF FOLLOW UP AFTER 2 MONTH	3(37.5%)



62.5% patients have come for regular follow up for one year.37.5% had lost follow up after 2 months .Among the married patients one lost follow up and the another one had follow up for one year.Initially she complianed of dyspareunia for 4 months and later it subsided.

CASES

FIGURE 12:A slight indentation or dimple may exist.

FIGURE 13: The dimple in the introital area is identified. The labia are retracted & a transverse incision is made in the epithelium.

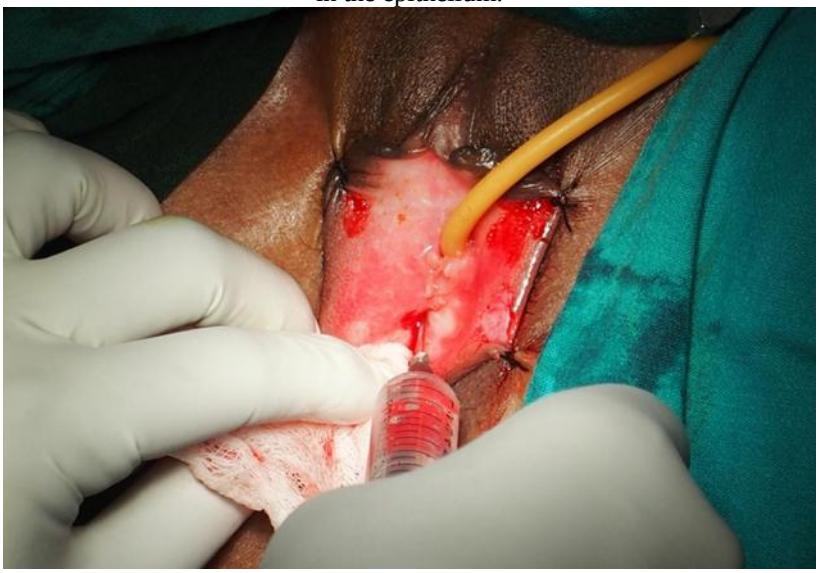


FIGURE 14: Blunt dissection with the fingers opens the space between the bladder and rectum.

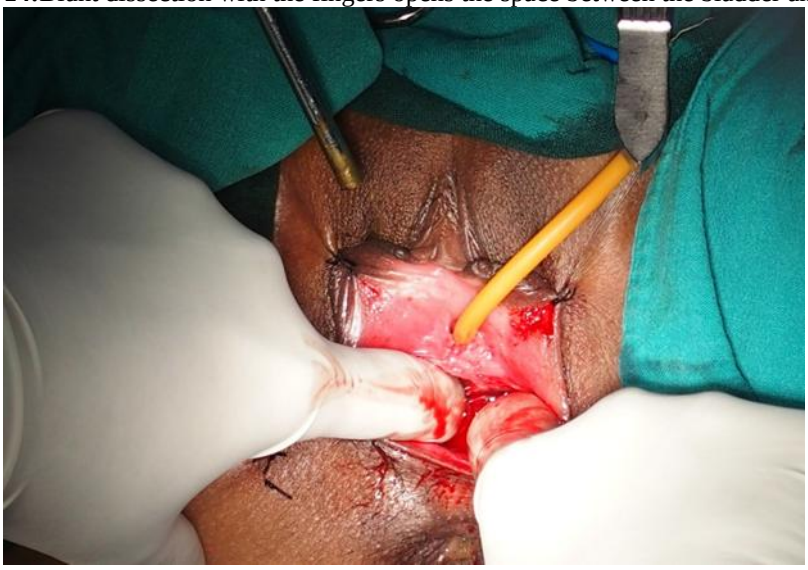


FIGURE 15:A sagittal section shows the dissection

FIGURE 16: Meticulous hemostasis should be maintained throughout the cavity.

FIGURE 17: Hematometra evacuation in one of the patients.Melacot's catheter was placed as a drain through the centre of the conformer for the passage of secretions.

FIGURE 18: The Sponge is Shaped into the desired vaginal form

FIGURE 19:The condom is slipped over the vaginal-form then the end of the condom is tied to make it air-tight.The vaginal form is laid on the epidermal side of the SSG. The graft is folded over the vaginal form & sutured [care not to puncture the condom while suturing].

FIGURE 20: The skin-covered form is inserted into the cavity.

FIGURE 21: To hold the form in place for 5 days, the labia are sutured in the midline with interrupted sutures without tension.

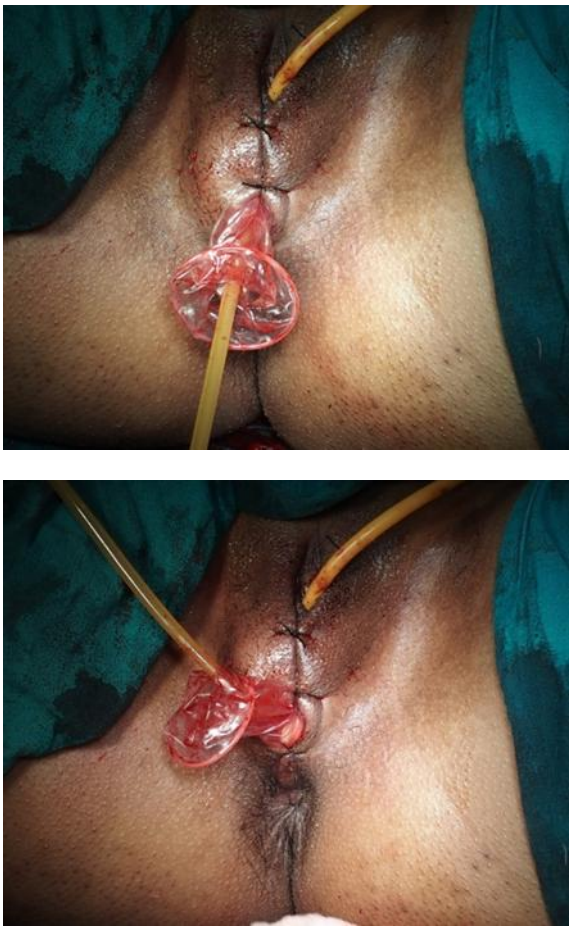


FIGURE 22: Mould formation

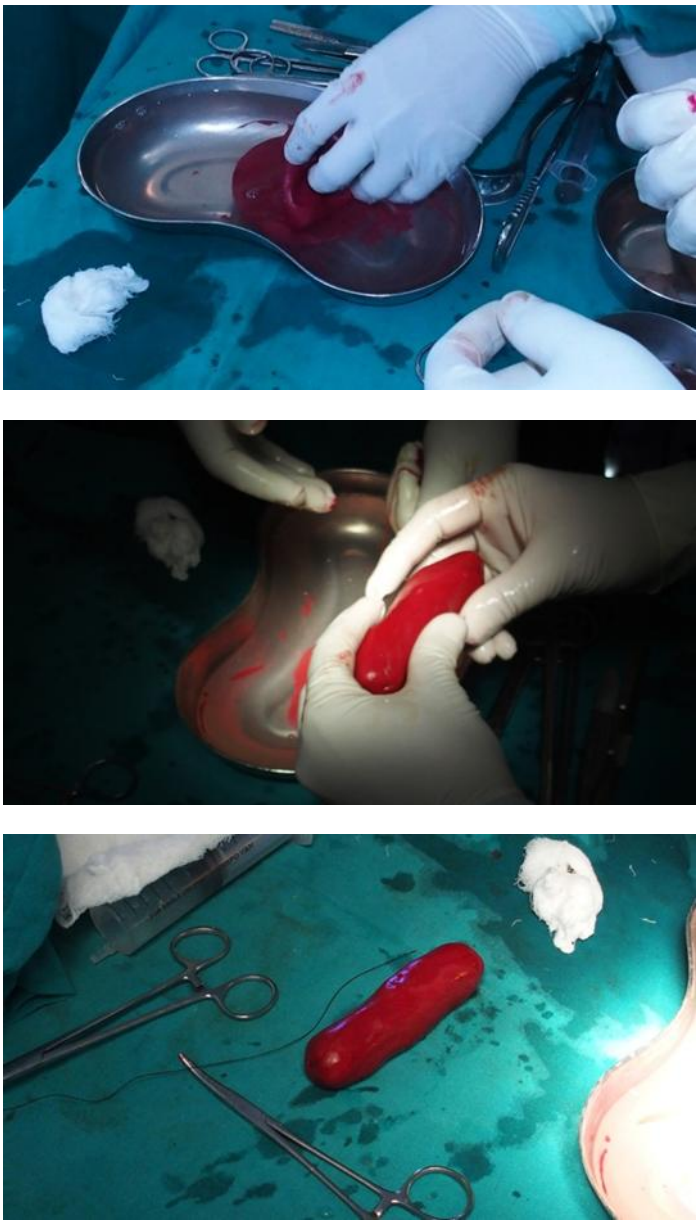


FIGURE 23:On 5th P.O.D., after thorough inspection and irrigation. A vaginal mould made of acrylic compound is be placed.

IV. Discussion:

In our study the youngest patient was aged 12 years and the oldest was aged 27 years (mean age 20 years).The commonest age group was 21 to 25 years. John A Rock et al study of 88 cases done in The John Hopkins hospital ,Baltimore describes the commonest presentation are usually at the age of 14 to 26 years and the mean age was 17 years. Lisa Jane et al study done in Los Angeles describes the commonest age of presentation is 15 to 18 years. Deepa kala et al is a retrospective observational study done in Mumbai.Out of 14 cases , 11 cases were at the age of 17-25 years. The mean age of the patients in the present study was 20 compared to 21 which was reported by John A Rock et al study. This data is consistent with epidemiological data by other authors such as Lisa Jane et al ,Deepa Kala et al

In our study primary amenorrhea was the presenting complaint of 75% patients. Most of the patients age group was above 15 who presented with the presenting complaint of primary amenorrhea. This is comparable to a study done by Ercan Bastu et al study, A.Menon et al study and Oya Soylu et al study.In Ercan Bastu et al study ,done in Istanbul between period of of 2002 to 2010,62 patients of vaginal agenesis were admitted ,among them 90% of the patient presented with primary amenorrhea as a presenting complaint.In Oya Soylu et al7 study done in turkey ,60% of the patients presented with a presenting complaint of primary amenorrhea.In A.Menon et al study,done in pune describes that the common presenting complaint is primary amenorrhea in vaginal agenesis

In our study cyclical lower abdominal pain was present in 25%patients and those patients who presented with cyclical abdominal pain was less than 15 years . In Chihiro Minami et al study and Deepa kala et al4 study stated that most of the girls in the age group below 15 ,presenting complaint was cyclical abdominal pain ,mostly due to hematometra /hematocolpous

In our study ,75% of them were unmarried and their age of presentation was below 24 years .25% of them presented with cyclical abdominal pain at the age below 15 years which was due to hematometra /hematocolpous and 75%presented with Primary amenorrhea ,above the age of 15 and below the age of 24.25%were married and mostly presented within 1 to 2 years after marriage.Those patients were above 24 years of age . Infertility was the main concern which led them to the treatment,which was similar to a study done by Donovan Dixon et al.In Donovan Dixon et al study 6 patients aged 17 to 28 years were included in the study which was done from april 2005 to august 2008 in Afgan women.Most of the women presented at the average age of 22 years soon after the marriage because of painful sexual intercourse or inability to accomplish intercourse.

In our study all the patients had developed secondary sexual characters. Axillary and pubic hair growth was present. Breast was developed. All the patients had gynaecoid pelvis. External genitalia development was normal. Labia majora and Labia minora were normal. None of the patients had clitoral enlargement. Vagina was replaced by a dimple measuring 1 to 3 cms.Our study was similar to A.Menon et al study.In A.Menon et al study3, describes that on clinical examination patient had well developed secondary sexual characteristics ,no androgen excess ,normal karyotype and primary amenorrhea and small blind vaginal dimple.On radiological absence of uterus with ovaries present was noted.

In our study on usg findings ,75% had normal ovaries and uterus .In Ercan Bastu et al study,among 23 patients only 2 patients had Normal uterus and ovaries.Among 21 patients,14 patients had both both hypoplastic uterus and hypoplastic ovaries and 7 patients had only hypoplastic ovaries In our study ,25% patients below the age of 15 years presented with cyclical abdominal pain for which MRI was adviced and in one patient at the age of 12 years , it showed a large blood filled cavity in uterus and in another patient at the age of 14 years it showed hypoplastic uterus filled with blood .27 years married female patient who presented with a complaint of primary amennorhea had both hypoplastic ovaries and hypoplastic uterus on MRI.In Do Young Kim et al5, A total of 463 cases of young women, aged 9–25 years, who underwent pelvic MRIs for various reasons from January 1995 to February 2019 at Seoul Asan Medical Center, were retrospectively reviewed. Patients were excluded from the study if they were not diagnosed with genital tract anomalies as determined by MRI. Among 463 patients, a total of 225 patients diagnosed with genital tract anomalies, as indicated by the final analysis using MRI, were included in the study.Among them 35 % was diagnosed to have MRKH.37%with hypoplastic uterus.4% with distal vaginal atresia

In our study 25% patients below the age of 15 with cyclical abdominal pain diagnosed as hematometra /hematocolpous was treated by draining of hematocolpos followed by Mc. Indoe's vaginoplasty.Rest of the patients who presented with primary amenorrhoea diagnosed to have vaginal atresia was treated by Mc. Indoe's vaginoplasty.In Donovan Dixon et al 8study 6 patients, aged 17 to 28 years with vaginal atresia was treated with Mc. Indoe's vaginoplasty. In Chihiro Minami et al6 study stated that most of the girls in the age group below 15 ,presenting complaint was cyclical abdominal pain ,mostly due to hematometra /hematocolpous was treated by draining of hematocolpos followed by Mc. Indoe's vaginoplasty.

In our study post operative mean vaginal length was 8.5 cms.In Ercan Bastu et al 2study,among 23 patients,the post operative mean vaginal length was 8.4 cms in 19 patients.None of the patients with post operative mean vaginal length was 8.4 cms experienced dyspareunia

In our study among 20 patients37.5% patients had graft loss and 25% patients had infection. In Cuneyt Ozek et al10 study among 29 patients ,post operative complications was seen in 10 patients.6patients had graft loss.

In our study all the patients used mould regularly as per the instructions In Donovan Dixon et al study 6 patients, aged 17 to 28 years with vaginal atresia was treated with Mc. Indoe's vaginoplasty had 100% compliance with mould.62.5% patients have come for regular follow up for one year.37.5% had lost follow up after 2 months .In Ercan Bastu et al study,among 23 patients,19 patients used the mould regularly. In Chandrashekar et al 9study,among 10 patients,8 patients had a regular follow up for one year

V. Conclusion

1. Most common age group of presentation was 21 -25 years females
2. Primary amenorrhoea was the most common presenting complaint
3. Most of the patients presented to us were unmarried
4. All the patients had developed secondary sexual characters
5. All patients had normal ovaries and uterus in USG and MRI
6. Mc.Indoe vaginoplasty is a simple and effective procedure for recreation of neovagina for vaginal agenesis,
7. Post operative mean vaginal length was 8.5 cms
8. Graft loss is common postoperative complication
9. Excellent results were observed in patients with proper mould usage after the surgery
10. Long term follow up of the patients had favourable results

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Statements & Declarations

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by all authors. The first draft of the manuscript was written by the corresponding author and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval

Approval for this study was granted by the Institutional Ethics Committee of Dr. KNR University of Health Sciences, Warangal, Telangana (Rc No. IEC/GMC/2021/01/12).

Consent to participate
Informed consent was obtained from all individual participants included in the study.

Consent to publish
The authors affirm that human research participants provided informed consent for publication of the images.

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