Review Article

Superiority of synthetic absorbable sutures over catgut suture in obstetric and gynecology surgeries — evidence based review

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Some perineal trauma has been reported in more than 85% of women having a vaginal birth. In the UK and US, spontaneous tears requiring suturing are estimated to occur in at least one-third of women. Perineal trauma may result in long-term physical and psychological problems. Despite a high birth rate in India, maternal morbidity due to high rates of episiotomy are grossly underreported and needs to be addressed at different levels such as restricted use of episiotomy procedures, enhancing skill of health-care professionals and implementation of evidence-based approach for training on globally acceptable surgical procedures to minimize episiotomy-associated complications. This review summarizes evidences available to support use of synthetic absorbable sutures over catgut sutures for episiotomy.

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More than 85% of women having a vaginal birth suffer some perineal trauma. Spontaneous tears requiring suturing are estimated to occur in at least one third of women in the UK and US. Perineal trauma can lead to long-term physical and psychological problems[1]. Episiotomy, an incision to perineum is performed during the vaginal child birth to ease the process labour or delivery. The commonly reported complications of episiotomy are postoperative perineal pain, dyspareunia, hematoma, and possible infection.

The incidence of episiotomy is quite high in developed as well as in developing countries, particularly in primi gravidae. In United States, 30-35% women who gave birth vaginally had an episiotomy during the labour process[2]. Kettle C *et al*, reported that the incidence of perineal trauma in the UK was high in women (85%) who had a vaginal birth, out of which 60-70% required suturing[2].

Unfortunately, very little information is available about episiotomy rates in India. Sathiyasekaran *et al* has reported an episiotomy rate at 67% (95% CI 62.6-71.4). They also observed that the risk of episiotomy was 4.1 and 2.2 times higher when conducted in tertiary level institutions and secondary level institutions compared to primary level institutions respectively. The authors reported that Episiotomy rate was very high (91.8%) during delivery in private medical college hospitals as compared to secondary and primary level institutions. Adjusted odds ratio for episiotomy was 38 when doctors conducted delivery compared to trained birth attendants and 8.9 when delivery was conducted at private medical college hospitals compared to primary health centres[3].

Saxena *et al* has reported around 71%episiotomy rate for vaginal deliveries at their institution[4], while Chhabra *et al*[5] found that overall episiotomy and vaginoperineal wound sepsis were the most common causes of postpartum admissions irrespective of the place of delivery. Home delivered women presented with unsutured infected perineal/vaginal tears whilehospital delivered ones hadinfected perineal, vaginal and cervical tears and infected episiotomies.

However, despite a high birth rate in India, maternal morbidity due to high rates of episiotomy is grossly underreported and needs to be addressed at different levels such as restricted use of episiotomy procedures, enhancing skill of doctors and nurses, and implementation of evidence based approach to train them on globally acceptable surgical procedures to minimize episiotomy associated complications.

In India, most of the surgeons/obstetricians/nurses are following the age old traditional way for episiotomy repair. Still, the plain catgut or chromic catgut sutures has remained the preferred choice for episiotomy, mainly due to their earlier experience of ease of use and local expert opinion and not because of evidences available.

Bharathi *et al* conducted a study to evaluate two different suture materials, namely, Vicryl Rapide and Chro-

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mic Catgut for episiotomy repair, in relation to a short term maternal morbidity. The authors reported that compared to the chromic catgut group, the Vicryl Rapide group was associated with less pain (32.5% *versus* 57%) and a less need for analgesia (15.5% *versus* 0.5) at 3-5 days, along with a significant reduction in the wound indurations, uncomfortable stitches and wound dehiscence (4% *versus* 13.5%) and a better wound healing ($p<0.05$ significant) in the Vicryl Rapide group. Wound infections (3.5%) and wound resuturing (2%) were seen in the chromic catgut group but were absent in the Vicryl Rapide group[6].

This report summarizes the evidences available to support use of synthetic absorbable sutures over catgut sutures for episiotomy procedures.

Catgut Sutures – History and current worldwide regulatory status :

Initially used as strings for instruments such as violin, fiddle, harp in 15th century, catgut sutures which are made from sheep intestine (collagen in nature) enjoyed popularity for long time because of number of reasons, such as high and good tensile strength, ability to reduce rapid degradation, good absorbability and augmenting biological response for tissue regeneration[7].

The European Union (EU) has taken a drastic decision of banning catgut sutures due to concerns over transmission of bovine spongiform encephalopathy (TSE, mad-cow disease), although there is no clinical evidence suggesting or supporting an association between transmissible TSE and catgut sutures. In a report from the European Commission's Scientific Committee on Medicinal Products and Medical Devices (in September 1998) opined that, in the light of the bovine and ovine origin of the material, and the classification of intestines as tissues of medium infectivity, special conditions have to be met in order to manage the risks related to TSE[8]. Plain catgut has a life of only 3 to 7 days, but if treated or coated with chromic salts to form the chromic catgut, it has an increased life up to 20-40 days. Chromic salts enhance the cross linking of collagen and prevent its rapid degradation. Thus, chromic catgut derived from sheep intestinal submucosa combines desirable aspects like natural origin, smooth surface due to coating or chromicisation, good tensile strength and absorbability. Since catgut is a resorbable suture, the material decomposes in the tissue interfaces and may be replaced by regenerating tissues, which augments its biological acceptance[8,9].

It is documented that T cells are largely responsible for the rejection of tissue transplants or implants. They enlist the aid of macrophages in destroying foreign cells and stimulate B cells to increase the production of antibodies by cell cooperation leading to the rejection of the implant if it is not prepared from carefully selected polymers and conditions that are biocompatible. But biocompatibility of plain and chromic catgut is well established and in concordance they did not provoke any adverse reactions leading to rejection in vegetarians. However adverse reactions and extrusion of plain and chromic catgut sutures were observed in 'mutton eaters' only. This could be possibly explained as follows. Mutton or sheep meat could contain certain proteins that elicit an immune response in people who consume them. In these people, the body could have produced certain antibodies in response to the mutton protein antigens. The specific memory B cells and T cells remain in their body for a long time andare long lived lymphocytes primed by their first contact with antigens. On renewed contact with the same antigen, these memory T cells and B cells can produce a secondary immune response, which is more rapid, vigorous, with higher and longer antibody titer.

Conclusion and recommendation from European commission – scientific committee[8,9] :

(1) Availability of sufficient alternative products to catgut sutures, ie, synthetic absorbable sutures made from polymers such as polyglycolic acid, that provide equal, or even better, clinical performance than the catgut. Apart from possibilities of occurrence of TSE with the latter, there are apparently no other differences between these two types of sutures with respect to matters of safety.

(2) There are no clinical indications for the preferred use of catgut. Moreover, scientifically there is no further need for catgut sutures.

(3) Based on considerations of the bovine origin and the classification of intestines as tissues of medium infectivity, special conditions must be met to manage the risks related to TSE with catgut.

(4) Manufacturing guidelines are stringent for any continued production of catgut.

(5) Guidelines for risk management as there are no known inactivation processes that can be applied to catgut, risk management cannot be achieved by this method.

(6) Revised CE approval process (requirement of justification) for medical devices using animal tissue in situations where satisfactory alternative materials are available.

Following the developments in other European countries and discussion with UK Medical Devices Agency (MDA), catgut suture manufacturers stopped supplying these to the UK market. The MDA supported the move as acceptable alternative synthetic sutures were available, and stressed there was no evidence of any health risk associated with catgut sutures[9]. However, the catgut sutures are still available in other countries including United States.

But the use of synthetic absorbable sutures exceeded the catgut sutures in last couple of decades the cited reason was inconsistent properties of natural materials, fear of transmission of TSE, associated inflammatory response

and availability of better clinical evidences for synthetic sutures[10].

Sutures available today are classified as permanent or absorbable, natural or synthetic, and multi-filament or monofilament. Multi-filament or braided sutures are easy to handle and have favourable knot-tying qualities. However, bacteria can enter the braided interstices and escape phagocytosis, potentially leading to suture infection, granulomas and sinuses. By contrast, monofilament sutures cause significantly fewer tissue reactions and glide easily through tissue. Their disadvantages include high retention of package shape, difficult handling, knot insecurity, and potentially cutting through tissue.

Absorbable Sutures : An overview

Absorbable sutures are characterized by the loss of most of their tensile strength within 60 days after placement. They should be absorbed with little or no tissue reaction at a predictable rate appropriate for the duration of the needed tissue support and are used primarily as buried sutures to close the dermis and subcutaneous tissue and to reduce wound tension. Absorbable sutures traditionally have not been recommended for skin closure, primarily due to unsightly railroad track formation. The only natural absorbable suture available is surgical gut or catgut sutures. Synthetic multi-filamentous materials include polyglycolic acid and polyglactin 910. Monofilamentous forms include polydioxanone, polytrimethylene carbonate, poliglecaprone, glycomer 631 and polyglytone. It is reported that original uncoated braided sutures from vicryl and one made of a homopolymer of glycolic acid) had rough surfaces and tendency to provoke inflammation and infection. To overcome this problem coated sutures like chromic catgut and dexon plus, with better tie down characteristics have replaced uncoated sutures.The use of absorbable material may be preferable because the sutures do not have to be removed, which saves the surgeon time and may lessen patient anxiety and discomfort.

Clinical evidences for synthetic absorbable sutures for episiotomy procedures :

The key parameters considered for reviewing the clinical database for synthetic absorbable sutures and catgut sutures are perineal pain, need for analgesia, wound dehiscence (impaired wound healing), dyspareunia, absorption profile (removal of suture material), local inflammatory response, infrction and physicochemical properties.

The meta-analysis on synthetic absorbable sutures in 'for primary repair of episiotomy and second degree tears' published in The Cochrane Library highlights the comparative clinical trials conducted with catgut sutures[11]. A total 11 trials with enrollment of 5072 women were considered in the review. Most of the parameters listed above were the comparative end points. The following section also highlights other studies which are not part of the Cochrane review.

(1) Pain — Postpartum pain is agonizing for a nursing mother, which has a great impact on the quality of life and on the nursing of the baby. Since Vicryl Rapide elicits less inflammatory tissue response than chromic catgut, it reduces the postpartum pain. Data from nine clinical trials involving 4017 women where pain was the primary outcome showed that fewer women in synthetic absorbable sutures group experienced less short-term pain compared to women in catgut suture group (risk ratio (RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90). Three trials also reported significantly less pain 10 days after delivery among women in synthetic absorbable group (RR 0.78, 95%CI 0.67 to 0.90, 2044 women). There was only one clinical trial which showed no difference between fast absorbing synthetic sutures and catgut sutures[11].

Other authors too showed that polyglactin 910 Rapide and polyglactin 910 is associated with either less pain, lesser short-term pain or mild pain compared to catgut sutures after episiotomy repair. In the early postpartum period, women in the polyglactin 910 Rapide group reported significantly lesser pain compared to other two groups ($P<0.05$) and by 30th day, all women in the same group were absolutely pain free in walking posture[12,13,14].

(2) Need for Analgesia — Analgesia use was measured as a secondary outcome in five clinical trials considered for Cochrane review. The women in the synthetic suture group had less number of analgesic use compared to catgut group (RR 0.71, 95%CI 0.59 to 0.87, five trials, 2820 women). Only one trial showed that the difference in analgesia use between groups was not statistically significant (RR 0.96, 95% CI 0.90 to 1.01)[11]. Kurian J *et al* also observed the similar findings in their study. At 7th day, 12% women in polyglactin 910 Rapide group required analgesics compared to 32% in polyglactine 910 and 50% in chromic catgut groups and by 42nd day, none of the women in polyglactin 910 Rapide required analgesics compared to 2% in polyglactin 910 and 4% in chromic catgut groups[12]. Similar observations were made by Shah *et al* where at analgesic requirement was slightly less in synthetic suture group compared to chromic catgut group[13]. while Bharathi *et al* reported that the difference in reduction in perineal pain between the two groups was statistically significant[6].

(3) Wound Dehiscence — Wound healing is a naturally occurring process. However, it depends on the types of the suture materials which are used, the presence or absence of an infection, etc. It also has an impact on the quality of life in the form of dyspareunia, incontinence of the bowel and bladder and pelvic floor dysfunction. While 15.7% of those with synthetic sutures had wound gaping, this applied to 25.5% of those with catgut sutures

(unweighted percentages). More women with catgut sutures required perineal re-suturing compared with those with synthetic sutures in the trials examining this outcome (RR 0.25, 95% CI 0.08 to 0.74, four trials, 1402 women)[11].

Shah *et al* have reported wound gaping were more in chromic catgut group where re-suturing was done in 1% of patients. However, wound healing process was good in synthetic suture group at day 20[13]. Sohail *et al* reported that 20% patients experienced mild pain on day 3 with chromic catgut, whereas as only 14% experienced mild pain with vicryl. None of the patients had dyspareunia after 3 months . The authors concluded that continuous suturing technique with either chromic catgut or vicryl is associated with less perineal pain and dyspareunia[14]. Dimitrov *et al* reported that patients with polyglycolic sutures showed better wound healing compared to catgut sutures. Additionally, noticeable scar was present in all women (replace patients with women) in catgut (42/42) versus 21/37 in polyglycolic sutures, out of which scar with granulation tissue (16/42 in catgut *versus* 3/37 in synthetic suture group) and wound gaping was also seen in 9/42 patients in catgut suture group versus none in synthetic suture group[15]. Bharathi *et al* reported that a wound discharge was observed in 3.5% of the cases and a wound infection was found in 4% of the cases in the Chromic Catgut group and they were observed in none of the cases in the Vicryl Rapide group[6].

Dyspareunia :

Ketcham *et al* showed that resumption of sexual activity was far better in synthetic sutures group (19/37) compared to catgut suture (1/42)[16]. The Cochrane review suggested that there was no significant difference in dyspareunia in patients with catgut or synthetic suturing[12]. The similar findings were observed by another group[15]. Bharathi et al reported that the uncomfortable stitches were less in the Vicryl Rapide group than in the Chromic Catgut group (24-48 hours 31.5% *versus* 48% , at 3-5 days 12.5% *versus* 27%), which was statistically significant ($p<0.05$) (24-48 hours 33% *versus* 40% , at 10th day 19% *versus* 26% with $p<0.001$). The lower rate of the uncomfortable stitches was related to the less tissue reaction of Vicryl Rapide and its rapid absorption[6].

(4) Removal of Suture Material — More women with standard synthetic sutures required the removal of unabsorbed suture material (RR 1.81, 95% CI 1.46 to 2.24, three trials, 2520 women)[12]. Kurian et al also reported similar findings in their study[12].

(5) Local inflammatory response — Pillai and Sharma have mentioned that catgut sutures elicit far more intense tissue reaction than synthetic absorbable sutures, because of their foreign protein structures. The local inflammatory response can be seen around the catgut sutures such as dense accumulation of macrophages, lymphocytes, and foreign body giant cells. After complete absorption, these are replaced by a dense mass of macrophages. The tissue reactions leading to exudates formation with tissue necrosis also reported with plain catgut sutures use[17]. In one retrospective study, it was observed the "rejection phenomenon" in patients sensitized to sheep protein mainly non vegetarians in whom catgut sutures were extruded from the wounds more often than vegetarians. Vicryl or prolene sutures were found to be not extruded in non-vegetarians[6]. Moreover a statistically significant reduction in the wound in duration was observed on the 3rd-5th days (7% *versus* 13.5%) in the same study[6].

(6) Infection — The infection rate in tissues containing the PGA suture was significantly less than the incidence of infection in tissue containing the gut sutures[17]. A wound discharge was observed by Bharathi *et al* in 3.5% of the cases and a wound infection was found in 4% of the cases in the Chromic Catgut group and they were observed in none of the cases in the Vicryl Rapide group. This was statistically significant with a p value of <0.05[8]. In one study, Leurox *et al*[18], reported that there was no infection at the site of the perineum repair in both the groups. In another study, Upton *et al*[19], reported that one woman in each group had an infection to the repair site.

(7) Physicochemical Properties — In one *in vitro* study, it was found that plain and chromic catgut disintegrated in pancreatic juice and pancreatic juice plus bile mixture. Polyglycolic acid and polyglactin 910 suture materials were vulnerable to pancreatic juice within 7 days. Polydioxanone retained most of its initial strength in pancreatic juice and bile. Polypropylene and silk retained 84% and 92% of their initial strength, respectively, showing polydioxanone was the strongest suture material in pancreatic juice[20,21]. An in vitro and in vivo evaluation of tensile strength in rat model showed that synthetic sutures proved to preserve its stability in all conditions but catgut lost its tensile strength in all medium. This in vitro study supports preferences of type of sutures in specific surgery[22].

The review article by Greenberg and Clark[23] summarizes the physical properties of various suture materials with respect to their use in obstetric and gynecologic surgery. The authors reported that there are currently 2 standards used to describe the size of suture material: the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP). The USP is more commonly listed. As expected, with all sutures increasing the size increases tensile strength. However, with both standards there is a marked reduction in the limits of the average minimum of knot-pulltensile strengths between collagen sutures and synthetic sutures for any given size.

The newer synthetic absorbable sutures have distinct advantages in obstetric and gynecological surgeries over the traditional natural collagen based catgut sutures[23].

Suture material is used in surgery to relieve healing tissues of disruptive forces. Because the degree of the for cevaries and the healing time needed for different wounds in different tissues varies, the sutures themselves should vary in their strength profiles. As noted above, minimum baseline suture tensile strengths are standardized by suture size and readily available from the USP. Yet, despite these minimum average standards, there is awide range of suture strengths among differing materials[23]. Each suture material has a recognized tensile strength which, for a given suture size, is most easily discussed as its failure or break load.This is the amount of weight in pounds or kilograms that is necessary to cause the suture to rupture. Typically, this measurement is presented in 2 forms, straight pull and knot pull, to reflect the reduction in any given suture's strength when it is knotted. In practical terms, the knot-pull tensile strength most accurately reflects a given smooth suture's in vivo tissue holding capacity. In a straight-pull tensile test, tension to rupture is applied at either end of a suture. A knot-pull tensile test is the same exceptth at a single knot has been tied in the middle of the strand[23].

All foreign bodies induce some degree of tissue reaction that impedes wound healing. The longer a suture material stays in the body, the more likely it is to serve as a nidus for undesirable tissue reactions that could delay and/or interfere with normal wound healing. Thus, the perfect suture material should retain adequate strength throughout the healing process and disappear afterward with minimal associated inflammatory reaction. Determining the balance between the added strength the suture provides to the tissues while they heal *versus* the negative effects of inflammation is central to choosing the proper sutures[23].

Thus in Sum, Level 1a and 1b evidence available for synthetic absorbable sutures over catgut sutures in perineal repair indicates a significant reduction in short terms pain with supportive data for reduction in long term pain, reduction in requirement of analgesic use, minimal local inflammatory reaction, relatively low incidence of re-suturing due to better wound healing and low incidence of wound gaping, higher incidence of removal of un-absorbed suture material and a lower infection rate. The other advantages of the synthetic sutures are their well-established superior biomechanical properties associated with good tensile strength, low tissue reactivity, easy to handle, low to high memory, predictable absorption and good knot security. Lastly, and more importantly, there are no exclusive indications for catgut sutures: their use is mainly driven by earlier experience and local expert opinion but not because the available evidences.

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