

SERRATIOPEPTIDASE (BIDANZEN) VS IBUPROFEN PARACETAMOL COMBINATION THERAPY IN EPISIOTOMY — A CLINICAL TRIAL

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SUMMARY

A total of 200 primiparas were studied where episiotomy was given. Out of them 100 patients were given antibiotic with serratiopeptidase (Bidanzen forte) tablet in dosage of 10 mg 8 hourly for 7 days. Other 100 women were given antibiotic with ibuprofen paracetamol combination therapy for seven days.

Serratiopeptidase therapy was found to be superior than ibuprofen paracetamol combination therapy for its antiinflammatory response in episiotomy. Thus pain was seen in only 24% cases of serratiopeptidase group than in 32% cases in other group. Tenderness, redness, swelling, induration were seen in 14%, 2%, 8% and 22% cases respectively in group I than in 26%, 11%, 16% and 32% cases respectively in group II. Dyspareunia was seen in 6% cases only in group I in contrast to 16% in group II. Routine use of serratiopeptidase tablets is recommended in all cases of episiotomy to lower maternal morbidity.

Introduction

Episiotomy is one of the commonest operations done in obstetrics and is the deliberate incision given in the perineum for easy delivery in primigravidas and before operative vaginal delivery (Myerscough, 1982). Although major complications due to episiotomy are rare, minor problems cause a lot of nuisance for the mother in the form of pain, swelling, induration and dyspareunia. Mediolateral episiotomy is preferred over midline episiotomy to decrease incidence of complete perineal tear (Barter et al, 1960; Coats et al, 1980).

Antibiotics and antiinflammatory agents are popular for decreasing maternal morbidity due to episiotomy. Ibuprofen, a phenyl propionic acid derivative is used for its antiinflammatory action and paracetamol, a para-aminophenol derivative is used for analgesic antipyretic action (Gilman, 1980; Crosslands, 1980). Serratiopeptidase a protease enzyme produced by *Serratia* E15 of the genus *Serratia* is used popularly for its antiinflam-

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matory action (Mori and Takekawa, 1967).

We studied antiinflammatory response of serratiopeptidase in 100 patients of episiotomy and compared its efficacy with ibuprofen paracetamol combination in other 100 patients.

Material and Methods

A total of 200 patients who delivered in Obstetrics and Gynaecology Department of Medical College and Hospital, Rohtak in whom episiotomy was given for primigravida indication were taken into the present study. Patients with episiotomy for other indications were excluded from the study to make the results comparable. Patients were divided in two groups:

I. Group - I: constituted by 100 patients who were given ibuprofen and paracetamol combination in dosage of 400 mg and 500 mg respectively thrice a day for seven days.

II. Group - II: was constituted by other 100 patients of episiotomy who were given 10 mg (20,000 units) or serratiopeptidase (Bidanzen forte) tablet thrice a day after meals.

Patients were examined on 1st day, 4th day and 7th day for any pain, redness, swelling, induration, tenderness and oedema at episiotomy site. Patients were called for follow up after 6 weeks to find any delayed complication and dyspareunia.

Results

All patients were primiparas with mean age being 20.15 years in group I and 21.2 years in group II. 95 patients in group I and 94 patients in group II were given right mediolateral episiotomy. Others were given median episiotomy.

As shown in Table I, it was observed that overall incidence of pain was 33% in

TABLE - I
SHOWING EFFECTIVENESS OF SERRATIOPEPTIDASE VS
IBUPROFEN PARACETAMOL COMBINATION THERAPY.

Sl. No.	Characteristics	Serratiopeptidase group (Group I) (%)	Ibuprofen paracetamol Group II (%)	P value	Significance
1.	Pain:				
	i) Mild pain	16	18		NS
	ii) Moderate pain	7	11	P<0.01	Signi-
	iii) Severe pain	1	4	P<0.01	ficant
2.	Tenderness	14	26	P<0.01	"
3.	Redness	2	11	P<0.05	"
4.	Swelling	8	16	P<0.05	"
5.	Induration	22	32	P<0.05	"
6.	Oedema	4	12	P<0.01	"
7.	Constipation	16	21	P<0.05	"
8.	Retention urine	6	7	P>0.01	NS
9.	Dyspareunia	6	16	P<0.01	Signi- ficant

ibuprofen paracetamol group in contrast to 24 percent in serratiopeptidase group, a statistically significant difference ($P < 0.01$) while there was no marked difference in mild pain in the two groups (18% vs 16%), moderate and severe pain were significantly lower in group II. Thus only 7 patients and one patient had moderate and severe pain respectively in study group, while 11 patients and 4 patients had so in control group a statistically significant difference (Table I).

Tenderness was present on 1st and 4th day in majority of the cases in the two groups, but on 7th day its incidence was less in serratiopeptidase group than in ibuprofen paracetamol group (14 percent Vs 26 percent) - a significant difference.

Redness was seen on 7th day in 2 cases of study group while it was seen in 11 percent cases in control group.

Swelling at the episiotomy site on 7th day was seen in 8 percent cases in study group than 16% in control group.

Induration was seen in only 22 percent of serratiopeptidase group than 32 percent in ibuprofen paracetamol group.

Oedema was seen in 4 percent case in group I than 12% in group II.

On follow up after 6 weeks incidence of dyspareunia was found to be only 6 percent in serratiopeptidase group and 16 percent in ibuprofen paracetamol group ($P < 0.01$).

Incidence of constipation was also more common in ibuprofen paracetamol group (16% Vs 21%).

Side effects of serratiopeptidase were seen in 3 cases only which included anorexia, nausea and slight gastric discomfort which got relieved on stoppage of

medicine.

Discussion

The deliberate incision of the perineum is almost always performed in primigravidae and before operative vaginal delivery. The operation, if performed without good judgement or repaired without due skill, can be the cause of considerable maternal discomfort and actual morbidity during the puerperium (Myerscough, 1982). It also contributes to sexual difficulty subsequently. Midline incision though has the advantage that no large blood vessels are encountered and the repair is very simple, it has the obvious disadvantage of its extension into the anal sphincter. Barter et al (1960) and Coats et al (1980) found incidence of third degree tears in midline episiotomies to be 12%. So mediolateral episiotomy is preferred.

To reduce the incidence of maternal discomfort antibiotics and antiinflammatory analgesics are recommended.

Ibuprofen, a phenylpropionic acid derivative has been clinically used since 1960s. In low dosage it may provide relief of pain without objective antiinflammatory effect (Gilman, 1980), while Acetaminophen (Paracetamol), a paraaminophenol derivative has analgesic antipyretic action but weak antiinflammatory activity (Gilman, 1980). Serratiopeptidase (Bidanzen from Biddle Sawyer Pvt. Ltd.) is a protease produced by serratia E15 of the genus serratia, which improves the circulation at the inflammatory focus by breaking down abnormal exudates and protein and by promoting the absorption of the decomposed products through the blood and lymphatic vessels and accelerates the elimination of sputum, pus and hematoma by breaking down and liquefy-

ing mucus secretion and fibrin clots and thus increases the concentration of antibiotics in the focus of infection and blood and is effective in episiotomy and pelvic inflammatory disease (Mori and Takekawa, 1967). It is also effective in acute cystitis when given with antibiotics (Sadanobu, 1967).

Our results were similar to other authors. We could find the drug to be very effective in the 100 patients studied. The results were better than with ibuprofen paracetamol combination therapy. Thus we could find incidence of pain to be only 24 percent in serratiopeptidase group than 33 percent in ibuprofen paracetamol group (Group II).

Tenderness, redness, swelling, induration, oedema, constipation and dyspareunia were all less common in serratiopeptidase group. Hence routine use of serratiopeptidase (10 mg) 8 hourly after meals for 7 days is recommended in all

cases of episiotomy to reduce maternal morbidity.

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