

## A PROSPECTIVE RANDOMISED STUDY OF THE EFFECT OF DILTIAZEM IN THE DRE AND PROCTOSCOPIC EXAMINATION

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### ABSTRACT

#### BACKGROUND

Digital Rectal Examination (DRE) and proctoscopy is an important routine investigation done by surgeons, gastroenterologists', etc. Most of the patients complain of pain and discomfort during the procedure. Anal sphincter complex contracts to the penetrating index finger as a voluntary reflex try to avoid hurting. A good lubricant jelly (with 2% lignocaine) and extreme gentleness should be the rule to this procedure to avoid discomfort and pain to the patients. Even with maximum precautions, majority of patients complain discomfort or pain during the procedure. To overcome this problem, we tried lubricant jelly and diltiazem gel combination.

#### MATERIALS AND METHODS

We evaluated 500 patients in this trial during the period 2010 to 2015 from the OPD of our institution with lubricant jelly alone and with diltiazem in the interval of two weeks. Analysis showed most of the patients is comfortable with combination lubricant jelly and diltiazem gel rather than lubricant jelly alone.

#### RESULTS

A total of 625 patients were screened for this study, but only 560 considered and enrolled (mean age 40 years). 60 patients failed to attend for the second examination, hence they were excluded from the final analysis.

#### CONCLUSION

The importance of DRE and proctoscopy known to every clinician, since it provides valuable information about anorectal pathology. Some patients are reluctant to give consent thinking that it will hurt them. By mixing lubricant jelly with diltiazem, the procedure becomes really comfortable due to good relaxation of anal sphincter complex.

#### KEYWORDS

Digital Rectal Examination (DRE)-Proctoscopic Examination-Lubricant Jell-Diltiazem-Anal Sphincter Complex-Sims Position.

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#### BACKGROUND

'If you don't put your finger in it, you risk putting your foot in it', this famous quote from Hamilton Bailey's well-known textbook, Demonstration of Physical Signs in Clinical Surgery shows the importance of digital rectal examination in surgical clinical assessment. It is a routine procedure for surgeons who are treating patients with anorectal pathology.

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It is considered to be very sensitive digital bio-probe to evaluate local as well as locoregional pathology, state of digestive tract and neuromuscular status.<sup>1</sup>

It is done by gently introducing lubricated index finger along the posterior aspect of anal canal, while the patient is lying in the left lateral position (sims).<sup>2</sup> It reveals indurations, tenderness, swelling in the anus, anal canal and lower part of rectum. The left lateral position (sims) is the most popular one for anorectal examination. Other rarely used positions are right lateral, dorsal, knee elbow and lithotomy positions. External sphincter is felt like a roll of tissue when contracted during examination. Internal sphincter is felt as narrow anal canal just 2.5 cm above the external sphincter.<sup>3</sup> Rectum proper is felt above the internal sphincter. Examiner can feel prostate in males and cervix in females anteriorly, while coccyx and sacrum is felt posterior. Laterally, ischioanal fossa, lateral wall of pelvis, lower end of ureter and internal

iliac arteries are felt. Ballooning of rectum is found in cases with obstruction above.

While proctoscopy helps to make visual assessment and minor surgical procedures. Usually, 2% lignocaine jelly is used as lubricant. Most of the patients feel discomfort during the procedure due to sudden contraction of anal sphincter complex, which is initiated by the contact of index finger at the sensitive anal and perianal region. The role of this chemical molecule, diltiazem is studied for the benefits, this imparts to DRE and proctoscopy. It is a calcium channel blocker like amlodipine, nifedipine and verapamil.<sup>4</sup> Calcium ions trigger contractions, while calcium channel blocker relaxes the smooth muscles by inhibiting the calcium channel function. They are mainly used as cardiac drug for the treatment of myocardial ischaemia. Recently, it has been advocated for the conservative management of fissure in ano.<sup>5</sup> Due to relaxation of anal sphincter complex, vasodilatation occurs and more blood is supplied to fissure, hence healing is enhanced.<sup>6</sup>

In our study, diltiazem hydrochloride 2% gel (w/w) is mixed with lubricant jelly (which contains 2% lignocaine) and is applied at the anal and perianal region and massaged for 2-3 minutes and procedure is conducted. Patient's acceptance is very high in this method. Examination done with lubricant alone and with combination of diltiazem in this study confirms the benefit of adding diltiazem to lubricant jelly. Procedure becomes painless and comfortable with combination. Aim of study was to compare the examination with lubricant jelly alone and with combination.

**MATERIALS AND METHODS**

This study conducted from 2009 to 2014 (5 years period) from the OPD of same institution. 500 patients are included in this trial (see Table 1).

**Inclusion Criteria-** Patients having complaints of itching, pain, discharge and bleeding per annum- Age group 25 to 55 years.

**Exclusion Criteria-** Aged patients and multigravidae were excluded- Fissure-in-ano, patients with excessive sphincter laxity, serious anorectal pathology and with severe medical diseases were also excluded from this study.

**Procedure-** Patient is placed in the left lateral position at the edge of the examination table and is told to breathe in and out deeply. A 3 cm length lubricant jelly and 0.5 cm length diltiazem gel taken on the palmar side of distal phalanx of index finger. It is gently placed on the posterior aspect of anus and is applied all around the circumference of anus and lower part of anal canal with gentle massaging for 2 to 3 minutes. After that finger is gently pushed higher into anal canal and rectum and procedure is completed. Examination during the first visit is done is done by using lubricant jelly (A) and after two-week procedure is conducted with lubricant jelly and diltiazem gel (B). Interval between two examination is not extended beyond two weeks, so patient can compare both. Following things are assessed whether examination with lubricant jelly and diltiazem is more comfortable than with lubricant jelly alone (x) or examination with lubricant jelly alone is more comfortable than combination (y) or there is no difference between two examinations (z). A self-reported questionnaire is given to patients for assessing the difference. The grading of pain is charted on Visual Analogue Scale (VAS). It is a horizontal line of 10 cm in length anchored by word descriptors at each end. Patients made mark on this line according the perception of pain or discomfort.<sup>7</sup> On the VAS, 0 means no pain and 10 means severe pain. Pain score during examination with lubricant jelly (A) varies from 5 to 8 (mean value-6.5) and with diltiazem (B) varies from 2 to 4 (mean value-3).

**Statistical Analysis**

Age Groups	Male (%) n-300	Female (%) n-200	Total (n-500)
25-30	75 (25)	20 (10)	95 (19)
31-40	125 (41.7)	80 (40)	205 (41)
41-50	52 (17)	60 (30)	112 (22.4)
51-55	48 (16)	40 (20)	88 (17.6)
Chi-square statistics 23.978; p value is 0.000025. The result is significant at p is <0.05.			

**Table 1. Distribution of Cases According Age and Sex**

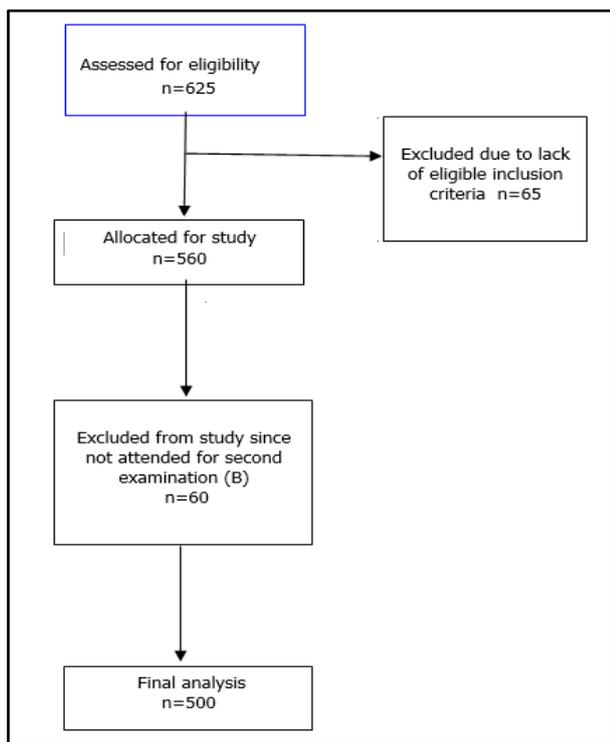
Age Group	Male n	Comfort Score X	Comfort Score Y	Comfort Score Z	Female n	Comfort Score X	Comfort Score Y	Comfort Score Z
22-30	75	64 (85)	6 (8)	5 (6.7)	20	16 (80)	2 (10)	2 (10)
31-40	125	112 (89.6)	5 (4)	8 (6.4)	80	64 (80)	6 (7.5)	10 (12.5)
41-50	52	44 (84.6)	2 (3.8)	6 (11.5)	60	52 (86.7)	0 (0)	8 (13.3)
51-55	48	40 (83.3)	2 (4.1)	6 (12.5)	40	34 (85)	2 (5)	4 (10)
	300	260 (86.7)	15 (5)	25 (8.3)	200	166 (83)	10 (5)	24 (12)
Chi-square statistics 4.4831, p value 0.611596; Chi-square statistics 5.5305, p value 0.477783								

**Table 2. Outcome of Patients Analysis**

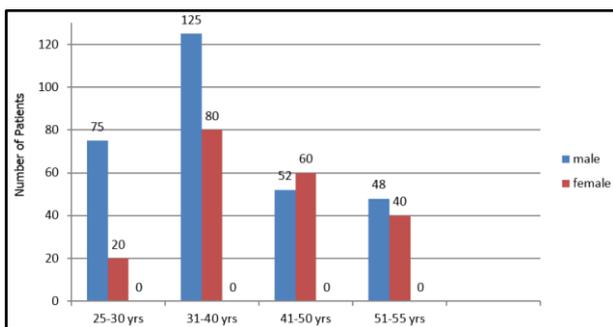
Values in parentheses are percentages.

**RESULTS**

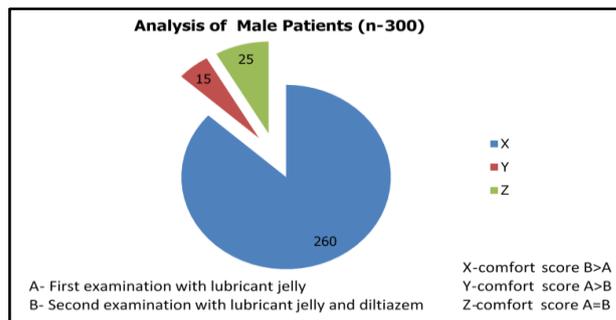
A total of 625 patients were screened for this study, but only 560 considered and enrolled (mean age 40 years). 60 patients failed to attend for the second examination, hence they were excluded from the final analysis (Figure 1 and 2). 86.7% of male patients (n=260) (Figure 3) are more positive with second examination (B) rather than 83% of female patients (n=166) (Figure 4). In males, 31-40 years age group (n=122) and females in 41-50 years age group (n=52) are having more favourable response in this examination (B), 89.6% and 86.7%, respectively. Comfort score is seen lower in 51-55 years in males (n=40) and 20-40 years in females (n=80). In nutshell, young males and old females, the comfort score is at higher level (x). On final analysis (Figure 5), 85.2% of patients (n=426) feels more comfortable with second examination (B) with lubricant jelly and diltiazem (x), whereas 9.8% of patients (n=49) doesn't feel any difference (z). 5% of patients (n=25) feels better(y) with lubricant jelly alone (A).



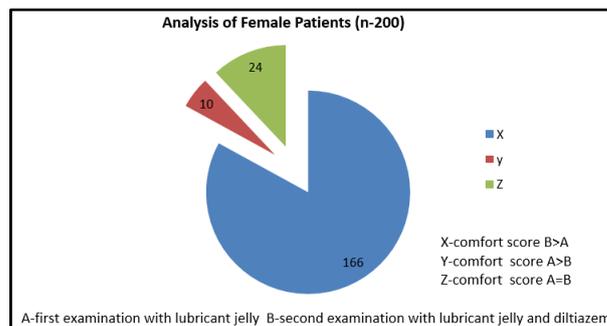
**Figure 1. Flow Chart of the Study**



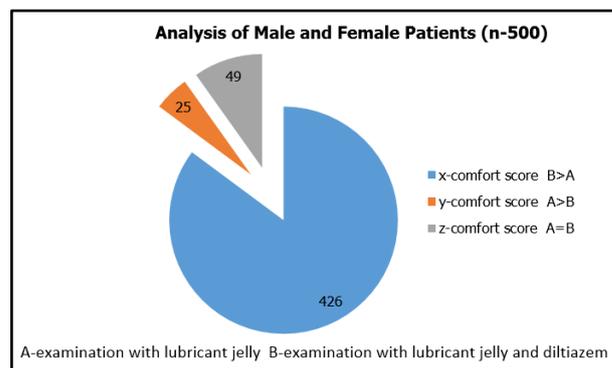
**Figure 2. Age and Sex Distribution of Patients**



**Figure 3. Analysis of Male Data**



**Figure 4. Analysis of Female Data**



**Figure 5. Final Data Analysis**

**DISCUSSION**

Though the digital rectal and proctoscopic examination gives a lot of worthy clinical information to the surgeon, the compliance on the part of patient towards this investigation is not always good. While usually considered safe, cheap and easy to learn, rectal examination maybe traumatic and poorly tolerated in children and a segment of adult population. Main reason behind this drawback is apprehension of being hurt by examiner. During examination, index finger has to overcome resistance produced by anal sphincter complex and anal canal. Anal resting pressure (normal value 40-80 mm of Hg) and voluntary squeeze pressure (above 40-80 mm of Hg) are produced by internal and external anal sphincters, respectively.<sup>8</sup> Internal sphincter is a smooth muscle and is always in a state of continuous maximum contraction, which is under autonomic control. Whereas, external sphincter is a weak voluntary muscle can maintain maximum contraction up to 30-60 seconds only.<sup>9</sup> In this context, relaxation of anal musculature is essential for proper evaluation. Diltiazem is a drug used to treat myocardial ischaemia by relaxing smooth muscle by blocking the calcium channel. Many studies confirm its value in the treatment of fissure in ano by

inducing vasodilatation by relaxing the anal sphincters.<sup>10</sup> This rationale is utilised in this study by mixing lubricant jelly with diltiazem. In these study, 85.2% patients confirm the beneficial effect of diltiazem by improved comfort score during the examination. In this observational study, whole information is provided by patients, which is subject to variation, moreover another major drawback is manometric measurement of anal resting pressure and squeeze pressure were not done during both examinations (A,B) from the OPD.

### CONCLUSION

The importance of DRE and proctoscopy known to every clinician, since it provides valuable information about anorectal pathology. Some patients are reluctant to give consent thinking that it will hurt them. By mixing lubricant jelly with diltiazem, the procedure becomes really comfortable due to good relaxation of anal sphincter complex. In our institution, we use this method for all patients. We recommends our colleagues to consider this combination.

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