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Original Article

Radiology Section

# Comparison of Percutaneous Instillation of Aqueous Jelly with Intravenous Contrast for Magnetic Resonance Fistulography- A Prospective Cohort Study

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## ABSTRACT

**Introduction:** The perianal fistulae are complex clinical scenarios, often complicated by direct or blind surgical exploration. A precise preoperative evaluation of the perianal fistulous tract is not only an essential diagnostic requirement but a presurgical prognostic determinant. The usefulness of Magnetic Resonance Imaging (MRI) in such instances is established, but if aqueous jelly can be used instead of regular contrast during fistulography is not clear.

**Aim:** To evaluate the diagnostic accuracy of Magnetic Resonance (MR) percutaneous aqueous jelly compared to intravenous (i.v.) contrast enhanced MR fistulography in perianal fistulous tracts.

**Materials and Methods:** A prospective cohort study was carried out on 40 participants who were referred for MR fistulography (with suspected anal fistulae) to the Department of Radiology, Mahatma Gandhi Medical College and Research Institute, Puducherry, India, form March 2017 to October 2019. Total 40 subjects presented with signs and symptoms of perianal fistula were injected with i.v. contrast and MR Fistulography sequences were obtained. Same subjects were injected with aqueous jelly two days prior to surgery and MR fistulography sequences were obtained. Both the sequences obtained were compared with respect to primary tract, internal opening and lateral ramification. These MR fistulography results were compared with intraoperative findings. Presence and absence of internal opening was analysed using Chi-square test for comparison of intraoperative internal opening and aqueous jelly internal opening. The specificity, sensitivity, Positive Predictive Values (PPV), Negative Predictive Values (NPV) and accuracy were estimated.

**Results:** Patients included in the study ranged from 25-65 years with a mean age of 41.5±7.3 years. Among the 40 subjects included, 37 were male and three were females. Aqueous jelly showed a good sensitivity of 96.67% overall in diagnosing internal opening as compared to intravenous (i.v.) contrast. Sensitivity and specificity of aqueous jelly in identifying internal opening was found to be 89.47% and zero respectively with an accuracy of 85% as compared to intravenous (i.v.) contrast in Grade I and II intersphincteric fistula. The PPV was 94.44% and NPV was found to be zero with respect to comparison of aqueous jelly with i.v. contrast grade I and II fistula.

**Conclusion:** Overall results of this study demonstrated that the instillation of the aqueous jelly is safe and provided diagnostic accuracy in identifying internal openings as compared to surgical findings.


**Keywords:** Anal fistula, Gadolinium, Intersphincteric fistula, Magnetic resonance imaging, Radiography

## INTRODUCTION

Perianal fistula classically present as an abnormal connection between the epithelial surfaces of canal to the perianal skin by an identifiable opening [1]. The prevalence of anal fistulae was observed to be 8.6 per 100,000 cases with a predominance of 12.3 per 100,000 cases in males as compared to 5.6 per 100,000 cases in females [2].

The anal fistulae are classified based as per the well-established Park's classification (based on the location of its tract in relation to the anal sphincter muscle) into 4 major types, namely intersphincteric, trans-sphincteric, suprasphincteric and extrasphincteric fistulae [3]. Also, based on St.James University Hospital classification, the perianal fistulas are classified into Grade I (simple linear intersphincteric fistula), Grade II (intersphincteric fistula with abscess formation or secondary tract) and Grade III (trans-sphincteric fistulae). The treatment modality for perianal fistula is based on its complex nature, severity, presence or absence of secondary tracts and abscess.

Surgery is the main stay of treatment for perianal fistula, however, it may lead to sphincter incontinence and recurrences due to over-excision and inadequate excisions [4,5]. In comparison to the operative findings, fistulography was the only imaging modality in the earlier days for the demonstration of anal fistula. Due to its unreliability to visualise anal sphincters and their relationship to fistula, Computed Tomography (CT) was used [6]. However, the use of CT has limited value due to its poor resolution in analysing soft tissues for anal fistulas [7]. Recently, the use of Magnetic Resonance Imaging (MRI) emerged as an efficient imaging modality for the preoperative classification of perianal fistulas. It helps in the direct visualisation of abscesses and tracts in combination to high soft tissue resolution. It can also identify the disease extension, which could otherwise be missed and affect the outcomes of patients. Hence, MRI was considered as a gold standard in the assessment and classification of anal fistulas [8,9].

The Magnetic Resonance (MR) with intravenous (i.v.) gadolinium is predominantly based on the enhancement of tract wall inflammation [4,10]. However, the exorbitant cost of gadolinium along with false positives and negatives has necessitated the usage of newer media [10]. In a study, percutaneous instillation of aqueous jelly into the sinus tract has enhanced the diagnostic efficacy of MR fistulography [1]. It increased the prominence of tracts by expanding the tracts and provided an intrinsic contrast by terminating the need for gadolinium administration. There are very few studies [1,11] available which compare the diagnostic accuracy of percutaneous instillation of aqueous jelly with other modalities. Therefore, to fill this paucity in literature, the current study was conducted to evaluate the effects and

diagnostic accuracy between MR fistulography using percutaneous aqueous jelly and i.v. contrast enhanced MR fistulography in comparison to surgical and intraoperative delineation.

## MATERIALS AND METHODS

This prospective cohort study was carried out on 40 participants who were referred for MR fistulography (with suspected anal fistulae) to the Department of Radiology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidiyapeeth (Deemed to be University), Puducherry, India, form March 2017 to October 2019. The approval of Institutional Human Ethical Committee Clearance (Reference number: ECR/451/Inst/PO/2013/RR-16) from affiliated tertiary care hospital, was obtained prior to commencement of the study. Written informed consent was obtained from subjects participating in the study.

**Inclusion and Exclusion criteria:** The patients of all age groups, both genders with signs and symptoms of anal fistula were included in the study. Patients who had a history of an allergy to the contrast medium, in cases where we were unable to cannulate external opening, those with impaired renal function, claustrophobics, MRI contraindicated patients (metallic prosthesis/cochlear implants) and those with previous perianal surgeries were excluded from the study.

Radiologists recruited all the eligible subjects into the study by convenient sampling method. All the subjects were followed-up for a period of 3 years according to the treatment regimen.

### Study Procedure

All the patients were injected with i.v. gadolinium (0.01 mL/kg body weight) in Diethylene Triamine Penta-Acetic acid (DTPA 0.1 mmol/kg at a rate of 1 mL/sec) agent and contrast enhanced MR fistulography sequences were obtained and fistulous tracts were assessed. The same group of patients (who were undergoing surgery) sorted into aqueous jelly group were subjected to percutaneous instillation of aqueous jelly (Tachyon Ultrasound jelly, Alex pharma, India), 1 or 2 days before surgery through external opening and MR fistulography sequences were obtained and fistulous tracts were assessed for diagnostic accuracy. The standards of MRI scan used are depicted in [Table/Fig-1].

| MRI specification | Non contrast scans | | | Non contrast fat suppressed scans | | Contrast enhanced fat suppressed scans |
|---|---|---|---|---|---|---|
| MRI sequences | T1W FSE | T2 W FSE | STIR | FST1 WFSE | FST2 WFSE | FST1 WFSE with 3D reconstruction |
| Imaging plane | Axial and coronal | Sagittal, axial and coronal | Axial and coronal | Axial | Axial and Sagittal | Sagittal, axial and coronal |
| TR/TE (m sec) | 820/min full | 5360/85 | 5825/50 | 1080/ min full | 4740/100 | 1060/min full |
| Field of View (FOV) | 36 | 36 | 36 | 36 | A=36 and S=30 | A=36 and S=30 |
| Section thickness/ spacing (mm) | 4/1 mm | 4/1 mm | 4/1 mm | 4/1 mm | 4/1 mm | 4/1 mm |
| Matrix | 384*256 | 384*256 | 384*224 | 384*256 | 384*224 | 384*224 |

**[Table/Fig-1]:** Standards and specifications of Magnetic Resonance Imaging (MRI) scan.
TE: Time to echo; RT: Repetition time; Fse: Fast spin echo; WFSE: Weighted fast spin echo; STIR: Short tau inversion recovery

During the percutaneous instillation of aqueous jelly, patients were placed in the prone position and external openings were identified. Sterile aqueous jelly was filled in a 10 mL syringe under aseptic conditions. The external openings were gently cannulated (20 G venous cannula attached to the syringe) by experienced radiologists. The patients were given approximately 3-5 mL of aqueous jelly per external opening ceased until the jelly started expelling out. MR fistulography of the patients was done immediately following the instillation of jelly using a 1.5 Tesla MRI scanner. The various sequences used in the study were T1W FSE, T2-weighted Fast Spin-Echo (T2W FSE), fat suppressed T1 with T2W FSE (axial, oblique and coronal), contrast enhanced T1W FSE fat-saturated (FAT SAT) and percutaneous installed aqueous jelly sequences (axial, coronal, sagittal), and T1 weighted sequences. [Table/Fig-1] provides the list of sequences for the Contrast-Enhanced MRI (CE-MRI) and the non contrast (jelly) MRI with important sequence details.

**Data collection:** Intraoperative/surgical findings were considered as the standard of reference and the diagnostic accuracies of CE-MRI and jelly-instilled MRI (jelly-MRI) and were subjected to comparison. The features such as the grade of fistulae, location of its internal opening, lateral ramifications were recorded and contrasted wherever necessary for diagnostic needs. The grade of fistulous tract was classified similar to that of Parks AG et al., [3]. Primary tract was defined as any tract arising from external opening and any lateral ramifications were defined as any secondary tract arising from primary tracts. Location of internal opening was based on 'O' clock position wherein, internal opening of fistula was based on the location of fistula in relation to anal clock. The 12 O'clock refers to anterior perineum, 6 O'clock to posterior perineum, 3 O'clock to left lateral aspect and 9 O'clock to right anal canal [12].

## STATISTICAL ANALYSIS

Data were interpreted using Statistical Package for the Social Sciences (IBM, SPSS version 22.0, USA). The presence and absence of internal opening was analysed using Chi-square test and the Odds ratio {with 95% Confidence Interval (CI)} was calculated for comparison of intraoperative internal opening and aqueous jelly defined internal opening. The specificity, sensitivity, Positive Predictive Values (PPV), Negative Predictive Values (NPV) and accuracy were calculated where in p-value <0.05 was considered statistically significant in all instances.

## RESULTS

Patients included in the study ranged from 25-65 years with a mean age of 41.5±7.3 years. Among the 40 subjects included, 37 were male and three were females. Out of the 40 patients, Grade III Transphincteric fistula was the most prevalent form observed and it accounted for 14 cases (35%) [Table/Fig-2].

| Parameters | Number (%) |
|---|---|
| **Gender distribution** | |
| Male | 37 (92.5) |
| Female | 3 (7.5) |
| **Grade distribution** | |
| Grade I | 8 (20) |
| Grade II | 12 (30) |
| Grade III | 14 (35) |
| Grade IV | 4 (10) |
| Grade V | 2 (5) |

**[Table/Fig-2]:** Demographic characteristics of study population.

The sensitivity, specificity, PPV, NPV and diagnostic accuracy of the aqueous jelly i.v. contrast in locating internal opening as opposed to identification on intraoperative way is shown in [Table/Fig-3].

With regards to the size, the mean length of fistulous tract in i.v. contrast group was 4.36 cm, whereas, the mean length of fistulous tract in the aqueous jelly group was 4.2 cm.

Among the 40 cases of perianal fistula, internal opening was detected intraoperatively in 32 cases, among this aqueous jelly located opening in 36 cases [Table/Fig-4]. The odds of internal

opening being detected were 16.51 times more with aqueous jelly as compared to i.v. contrast.

| Methods compared | Sensitivity | Specificity | Accuracy | PPV | NPV |
|---|---|---|---|---|---|
| Aqueous jelly vs intraoperative | 93% | 90% | 92.5 % | 96.5% | 90% |
| Intravenous contrast vs intraoperative | 96% | 90% | 95 % | 96.6% | 90% |
| Aqueous jelly vs i.v. contrast (over all) | 96.67% | 100% | 97.5% | 100% | 90.9% |
| Aqueous jelly vs i.v. contrast (grade I, II fistulae) | 89.47% | 0 | 85% | 94.44% | 0 |
| Aqueous jelly vs i.v. contrast (grade III-V fistulae) | 100% | 33.33% | 80% | 77.77% | 100% |

**[Table/Fig-3]:** Comparison between aqueous jelly intravenous (i.v.) contrast and intra operative methods in delining internal opening of perianal fistula.

| Medium used | Intraoperative internal opening | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| **Aqueous jelly internal opening** | | | | |
| Present | 31 | 5 | 36 | 0.019* |
| Absent | 1 | 3 | 4 | |
| Total | 32 | 8 | 40 | |
| **Intravenous (i.v.) contrast internal opening** | | | | |
| Present | 28 | 5 | 33 | 0.13 |
| Absent | 4 | 3 | 7 | |
| Total | 32 | 8 | 40 | |

**[Table/Fig-4]:** Comparison of MR fistulographic internal opening findings with intra operative internal opening.
*p<0.05 is considered statistically significant; Test used: Chi-square test

Comparison of aqueous jelly with i.v. contrast in delineating internal opening was presented in [Table/Fig-5]. Considering i.v. contrast as the gold standard, out of 40 cases, aqueous jelly detected 36 cases.

| Aqueous jelly internal opening | Intravenous (i.v.) contrast | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| Present | 31 | 5 | 36 | 0.13 |
| Absent | 2 | 2 | 4 | |
| Total | 33 | 7 | 40 | |

**[Table/Fig-5]:** Comparison of aqueous jelly with intravenous (i.v.) contrast in delineating internal opening of perianal fistula.
Chi-square test

A total of 20 cases were presented with Grade I and II intersphinteric fistula. Intravenous contrast detected internal openings in 19 cases as compared to aqueous jelly which detected internal openings in 18 cases [Table/Fig-6].

| Aqueous jelly internal opening | Intravenous contrast internal opening | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| **Simple Grade I and II intersphincteric fistula** | | | | |
| Present | 17 | 1 | 18 | 1.00 |
| Absent | 2 | 0 | 2 | |
| Total | 19 | 1 | 20 | |
| **Grade III, IV and V trans-sphincteric fistula** | | | | |
| Present | 14 | 4 | 18 | 0.08 |
| Absent | 0 | 2 | 2 | |
| Total | 14 | 6 | 20 | |

**[Table/Fig-6]:** Comparison of aqueous jelly with intravenous (i.v.) contrast in delineating internal opening in different gradings of fistula.
Chi-square test

Sensitivity and specificity of aqueous jelly in identifying internal opening was found to be 89.47% and 0% respectively with an accuracy of 85% as compared to i.v. contrast in Grade I and II intersphincteric fistula. The PPV was 94.44% and NPV was found to be zero [Table/Fig-3].

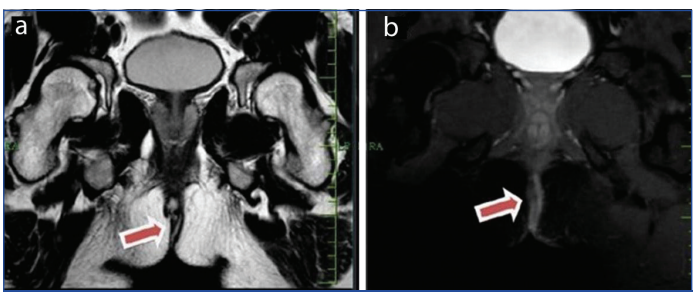
Among the 20 cases of Grade III, IV and V trans-sphincteric fistula, i.v. contrast detected internal opening in 14 cases and aqueous jelly detected internal openings in 18 cases [Table/Fig-6]. Hence, aqueous jelly was found to be 100% in identifying internal opening in Grade III, IV and V trans-sphincteric fistula in comparison to i.v. contrast. However, specificity was found to be 33.33% with an accuracy of 80%. The PPV and NPV were observed to be 77.77% and 100% respectively [Table/Fig-3].

Among the 20 cases with Grade I and II intersphincteric fistula, 18 cases showed internal opening per operatively. With respect to MR Fistulography (sequence of both i.v. contrast and aqueous jelly), 17 cases showed internal opening. The results demonstrated that there was no statistically significant difference between per operative and MR Fistulography findings with respect to internal opening for Grade I and II intersphincteric fistula. The sensitivity and specificity were observed to be 88.88% and 50% with 94.11% and 33.33% of PPV and NPV. Accuracy of detection was found to be 85%. With regards to Grade III, IV and V trans sphincteric fistula, both MR Fistulography and per operative findings detected 14 cases with sensitivity and specificity of 78.57% and 50%, respectively. The accuracy was observed to be 70% [Table/Fig-7].

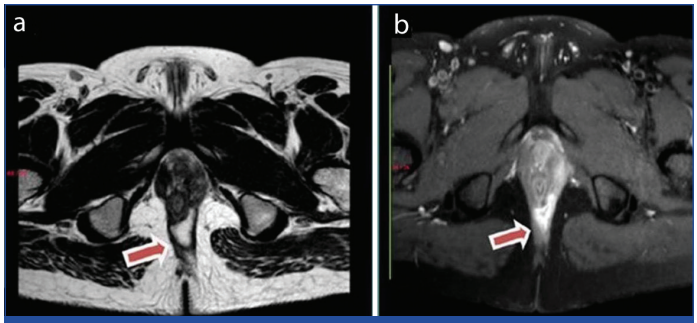
| Intravenous contrast/ Aqueous jelly internal opening | Intraoperative internal opening | | Total | p-value |
|---|---|---|---|---|
| | Present | Absent | | |
| **Simple Grade I and II intersphincteric fistula** | | | | |
| Present | 16 | 1 | 17 | 0.28 |
| Absent | 2 | 1 | 3 | |
| Total | 18 | 2 | 20 | |
| **Grade III, IV and V trans-sphincteric fistula** | | | | |
| Present | 11 | 3 | 14 | 0.29 |
| Absent | 3 | 3 | 6 | |
| Total | 14 | 6 | 20 | |

**[Table/Fig-7]:** Comparison of MR Fistulographic internal opening findings with intraoperative surgical findings in different grading of perianal fistula.
Chi-square test

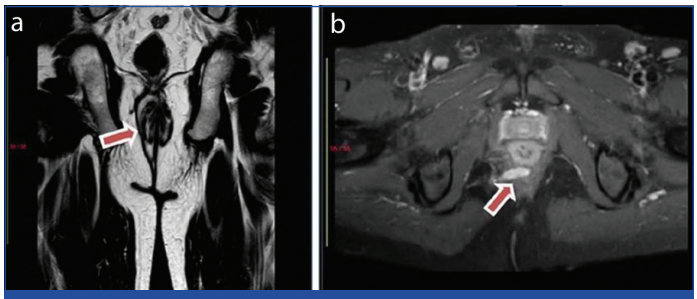
Detection of primary tract in i.v. contrast/aqueous jelly MR fistulography in comparison with surgical findings showed 100% sensitivity, 100% specificity and 100% diagnostic accuracy. With regards to lateral ramifications, i.v. contrast showed 100% sensitivity as compared to aqueous jelly which showed 80% sensitivity. Intraoperatively, lateral ramifications were not delineated accurately [Table/Fig-8-11].



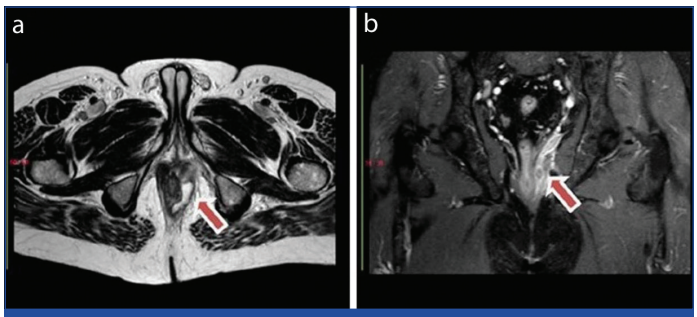

**[Table/Fig-8]:** Patient with grade I Intersphincteric fistula: a) Axial T2 weighted sequence with aqueous jelly; b) Axial T1 weighted sequence with i.v. contrast) demonstrate simple grade I Intersphincteric fistulous tract (arrowhead).




**[Table/Fig-9]:** Patient with grade II intersphincteric fistula with abscess: a) (Axial T2 weighted sequence with aqueous jelly) and b) (Axial T1 weighted sequence with i.v. contrast) demonstrate horseshoe abscess (arrowhead) in Intersphincteric space.




**[Table/Fig-10]:** Patient with grade IV intersphincteric fistula: a) (Coronal T2 weighted sequence with aqueous jelly) and b) (Axial T1 weighted sequence with i.v. contrast) demonstrate trans-sphincteric fistulous tract (arrowhead).




**[Table/Fig-11]:** Patient with grade II intersphincteric fistula with abscess: a) (Axial T2 weighted sequence with aqueous jelly) and b) (Coronal T1 weighted sequence with i.v. contrast) demonstrate intersphincteric fistulous tract with abscess formation (arrowhead) in intersphincteric space.

## DISCUSSION

Magnetic resonance fistulography provides a good preoperative roadmap for delineating perianal fistulous tract for surgeons. The preoperative evaluation of perianal fistulas with the advent of MR with its excellent soft tissue contrast and multiplanar imaging capabilities makes it an ideal choice as compared to the surgical exploration.

In the current study, aqueous jelly showed a good sensitivity of 96.67% in diagnosing internal opening with a statistically significant difference of 0.019. Whereas, i.v. contrast showed a sensitivity of 87.5% in diagnosing internal opening. These results were similar to the study conducted by Torkzad MR and Karlbom U wherein a comparison was made between i.v. contrast and aqueous jelly T1 and T2 weighted imaging protocol [12]. The study results showed that the aqueous jelly was found to be 100% sensitive compared to i.v. contrast which showed 96% sensitivity. Similar study conducted by Aggarwal R et al., [1] showed 94.2% sensitivity and 100% specificity with aqueous jelly in identifying the internal opening. In the current study, the specificity was less but sensitivity was comparable with aqueous jelly.

Comparison of aqueous jelly with i.v. contrast on Grade I and Grade II intersphincteric fistula showed 89.5% sensitivity. With regards to the Grade III, IV and V, the sensitivity was significantly higher for aqueous jelly as compared to i.v. contrast MRI [13]. On review of literature similar studies in this regard are absent. Thus, this is the first study conducted wherein the comparison of aqueous jelly with i.v. contrast for detecting the sensitivity of internal opening on different grades of perianal fistula was carried out.

The overall comparison of MR imaging (aqueous jelly/i.v. contrast) with intraoperative surgical findings showed that there was no statistically significant difference between per operative and MR Fistulography findings with respect to internal opening for Grade I and II intersphincteric fistula. However, comparison of MR imaging (aqueous jelly/i.v. contrast) with intraoperative surgical findings with regards to grade III, IV and V showed that both MR Fistulography and per operative findings detected 14 cases. In contrast to our findings, a study conducted by Morris J et al., reported MR imaging grades I and II were associated with satisfactory outcome as compared to grades III, IV and V which produced unsatisfactory outcome mandating the requirement of surgery [14].

The sensitivity of lateral ramification in the present study was 80% sensitive and 100% specific in delineating lateral ramification. A study conducted by Aggarwal R et al., also concluded sensitivity and specificity to be 90.5% and 100% in demarcation of lateral ramification with aqueous jelly [1]. Hence, it was concluded that the sensitivity of lateral ramification was less in aqueous jelly. The advantage is lies in methodology of incorporating use of alternative for i.v. contrast.

### Limitation(s)

The limitations such a smaller simple size and study conducted at a single centre do exist, call for larger population studies.

## CONCLUSION(S)

Percutaneous instillation of aqueous jelly prior to MR fistulography provides an accurate delineation of the complex anatomy of fistulae. This novel technique was proved to be reliable in detecting internal openings, and primary tract. The current study establishes a baseline data for anal fistulae in this specific geographical location. The accuracy of detection is significant to map the various complications and extent of disease in future.

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