Diagnostic Accuracy of Three-Dimensional Endoanal Ultrasound for Anal Fistula: A Systematic Review and Meta-analysis

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ABSTRACT

Background: Anal fistula is a relatively common anorectal disease. An accurate assessment of the main anal fistula type and the anatomy of the internal opening before surgery is necessary to obtain the best surgical results. Whether three-dimensional endoanal ultrasound (3D-EAUS) should be used as the first-line diagnostic tool for anal fistula is still controversial. The purpose of this study is to conduct a meta-analysis of the published literature on 3D-EAUS and anal fistula, and compare the results of 3D-EAUS and surgery to evaluate the diagnostic value of 3D-EAUS for anal fistula.

Methods: An online search of databases in English included PubMed, Embase, and Cochrane Library. After the diagnostic accuracy of 3D-EAUS of all anal fistula types was integrated, a single-group rate meta-analysis was performed; we analyzed 3D-EAUS separately for the diagnosis of different anal fistula types, and conducted a meta-analysis of test accuracy. The analysis combined sensitivity, specificity, and the respective 95% CI, to draw a summary receiver operating characteristic curve (SROC), and estimate the area under curve (AUC).

Results: Based on the inclusion criteria, we selected 8 studies covering 1057 cases of anal fistula and 548 cases of internal opening. The meta-analysis data show that 3D-EAUS has a total accuracy rate of 91% (95% CI, 88-94%). It has high sensitivity and specificity for different anal fistula classifications. The SROC curves for anal fistula internal openings were plotted, and the AUC was calculated to be 0.86 (95% CI, 0.83-0.89).

Conclusions: 3D-EAUS can be used as the first-line diagnostic tool for anal fistula, because it has a high diagnostic accuracy for most anal fistulas. However, due to the insufficient diagnostic accuracy of 3D-EAUS for complex fistulas, 3D-EAUS combined with MRI examination can be used to more accurately detect the secondary extension of complex fistulas, so as to describe the complete anatomy of the fistula in more detail.

Keywords: Ultrasound, endoanal, three-dimensional, anal fistula, meta-analysis

INTRODUCTION

Anal fistula is a relatively common anorectal disease, usually occurring in young adults aged 21-42 years. Some studies have pointed out that the incidence of anal incontinence after anal fistula surgery is 0-40%, and the recurrence rate is 0-26.5%.^{1,2} The reason may be that the internal openings were not accurately identified before the operation, the fistula was not completely treated, the fistula branch was missed, or the shape of the fistula was not understood, etc., resulting in excessive intraoperative anal sphincter injury.³ Therefore, accurate preoperative assessment of the main anal fistula type and the anatomy of the internal opening is necessary to obtain the best surgical results.^{1,2} Some medical centers prefer to use the transrectal twodimensional ultrasound to assess the perianal area, which has good sensitivity and specificity for anal fistula.⁴ In recent years, the appearance of three-dimensional endoanal ultrasound (3D-EAUS) has further improved the ability to diagnose anal fistula.⁵ It provides detailed anal canal multiplanar reconstruction and improves the accuracy in observing fistula trajectory and internal opening identification.³⁶

Whether 3D-EAUS should be used as the first-line diagnostic tool for anal fistula is still controversial. Related studies have shown that 3D-EAUS has a high degree of consistency in the identification of anal fistula types and internal openings with surgery, which is sufficient for

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Corresponding authors: Fei Chen or Shao-Dong Qiu, e-mail: flyly@126.com or shaodongqiu@126.com Received: August 17, 2020 Accepted: February 23, 2021 Available Online Date: November 25, 2021 © Copyright 2021 by The Turkish Society of Gastroenterology · Available online at turkjgastroenterol.org DOI: 10.5152/tjg.2021.20750 preoperative evaluation of fistulas. The 3D-EAUS examination is also recommended as the preferred examination method for patients with anal fistula.⁷ However, Rishi Philip Mathew believes that 3D-EAUS is not as good as MRI in identifying and assessing suprasphincteric fistulas, external sphincter fistulas, or secondary expansion. It may provide the surgeon with incomplete or even inaccurate information, leading to incomplete surgical treatment, which may cause recurrence.⁸ The limitation of 3D-EAUS is that it is difficult to distinguish between fistula and scar tissue, because both tissues show low echo on 3D-EAUS.⁴ In addition, a very strong reflection occurs at the gas/tissue interface, so that any details deep in the interface are blocked.⁶

At present, there are still different opinions about the accuracy of 3D-EAUS in the diagnosis of anal fistula. The purpose of this study was to conduct a meta-analysis of the published literature on 3D-EAUS and anal fistula, and compare the results of 3D-EAUS and surgery to evaluate the diagnostic value of 3D-EAUS for anal fistula.

MATERIALS AND METHODS

The study was executed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement,⁹ and was registered at INPLASY (number INPLASY202070090, DOI number 10.37766/inplasy2020.7.0090).

The online search of databases in English included PubMed, Embase, and Cochrane Library. The search string used was ("fistula"/exp OR "fistula, rectal": ab, ti OR "anal fistula": ab, ti AND "ultrasound'/exp AND endoanal), covering the period from the establishment of each database to June 2020; the search language was English. In order to minimize the possibility of any missed search results, a secondary search of all references was performed.

Study Selection and Data Extraction

Two researchers independently screened the literature, extracted data, and evaluated the quality of the included research methodology. Study quality was independently assessed using a tool for the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2).¹⁰ Conflicts in data extraction were resolved by a third reviewer.

Inclusion and Exclusion Criteria

The inclusion criteria for the study were a 3D-EAUS diagnostic test with diagnosis of anal fistula; complete data; and the gold standard of a pathological biopsy. Reviews, conference reports, and cases with missing data were excluded. If there were multiple reports of the same study, the one with the latest and most comprehensive literature was included.

OUTCOME MEASURES

The main outcome indicator considered was the accuracy of the fistula, the secondary outcome indicators were as follows: type of fistula (intersphincteric fistula, transsphincteric fistula, suprasphincteric fistula, extrasphincteric fistula, superficial fistula) and internal opening position.

Statistical Analysis of Data

STATA 15.1 and RevMan 5.3 software were used for data analysis. After the diagnostic accuracy of the 3D-EAUS of all anal fistula types was integrated, a single-group rate meta-analysis was performed; 3D-EAUS were analyzed separately for the diagnosis of different anal fistula types, and a meta-analysis of test accuracy was conducted. The heterogeneity was evaluated by I^2 value, with an $I^2 < 25\%$ suggesting less heterogeneity between studies, I² 25 ~ 50% suggesting moderate heterogeneity, and I^2 > 50% suggesting high heterogeneity. If heterogeneity was indicated, we used the method of subgroup analysis to find the possible sources of heterogeneity. The random effects model (REM) or fixed effects model were chosen according to the degree of heterogeneity. We combined sensitivity, specificity, and respective 95% confidence interval (95% CI), to obtain a summary receiver operating characteristic curve (SROC) and to estimate the area under curve (AUC). This study conducted a subgroup analysis of 2 covariates-the study population and the use of instruments. Publication bias diagnosis and sensitivity analysis were performed for the included studies. The diagnostic performance of 3D-EAUS for various types of anal fistula was evaluated using the Youden index. The above inspection levels were $\alpha = 0.05$.

RESULT

A total of 12 articles were included.¹¹⁻²² The flow chart of document retrieval is shown in Figure 1. The basic information contained in the literature is shown in Table 1. A total of 1057 fistulas were included. According to the Parks classification, there were 241 intersphincteric fistulas, 667 transsphincteric fistulas, 73 suprasphincteric fistulas, 8 extrasphincteric fistulas, 19 superficial fistulas, and 548 internal openings (Table 2). The QUADAS-2 scale was used to score the quality of the 12 articles finally included, as shown in Figure 2.



Figure 1. Flow diagram of literature search.

Accuracy of Fistula Type

When the result of 3D-EAUS diagnosis of fistula was consistent with surgery, it was defined as positive; otherwise it was defined as negative. Thus, the accuracy rate was calculated. When the normality test indicated that the data conformed to the normal distribution, a single-rate meta-analysis was performed, as shown in Table 2.

Table 1. Basic Information In	ncluded in the Literature
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Author	Year	Country	Cases	Age	Sex	Inclusion Period	Region	Ultrasonic Instrument
Almeida	2019	Sri Lanka	87	75/12	Unclear	1, 2009-1, 2016	Asia	Olympus
Brillantino	2015	Italy	212	121/91	33-57	1, 2009-1, 2013	Europe	BK Medical
Brillantino	2019	Italy	124	Unclear	Over 18	1, 2014-1, 2017	Europe	BK Medical
Buchanan	2005	England	19	15/4	17-66	12, 2000-8, 2002	Europe	BK Medical
Garces	2010	Spain	29	Unclear	Over 18	12, 2008-8, 2009	Europe	BK Medical
Garces	2014	Spain	70	51/19	21-77	Unclear	Europe	BK Medical
Ghafoori	2016	Iran	36	23/13	26-54	12, 2013-2, 2015	Asia	BK Medical
Kim	2009	Korea	61	37/24	17-74	1, 2007-1, 2009	Asia	BK Medical
Kolodziejczak	2017	Poland	299	202/97	17-90	12, 2008-4, 2011	Europe	BK Medical
Low	2013	Malaysia	28	22/6	19-62	6, 2008-1, 2011	Asia	BK Medical
Mantoo	2020	Singapore	68	Unclear	29-57	1, 2017-1, 2018	Asia	BK Medical
West	2004	Netherlands	21	18/3	26-71	4, 2000-4, 2002	Europe	BK Medical

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Author	Concordance With Surgery, %	Cases	ЧT	Ę	Z L	Z	Ę	БР	Z	Z⊢	ЧT	БР	Z	Z⊢	ТР	БР	Z	NL	ΤЬ	БР	Z	N
Almeida	0.713	87	~	7	5	62	54	12	ω	13	0	-	e	83				1	0	0	ю	0
Brillantino	0.943	212	47	0	7	163	104	2	0	103	9	0	ო	203	2	0	0	210	2	0	2	205
Brillantino	0.977	132	31	0	-	100	80	0	-	51	7	-	0	124	2	-	0	129	4	0	0	122
Buchanan	0.905	21	0	0	-	20	16	0	2	ю	-	0	0	20	ī	ī	ı	ı	0	0	-	20
Garces	0.931	29	ß	0	2	22	22	-	0	9	ī	ı	ı	ı	ı	ı	ı	ı	ī	ī	ī	ı
Garces	0.929	70	6	-	4	56	56	4	-	6	ī	ī	ī	ī	ī	ī	ı	ī	ī	ī	ī	ī
Ghafoori	0.943	35	9	0	2	27	27	2	0	9	ī	ī	ī	ī	ı	ī	ı	ı	ī	ī	ī	ı
Kim	0.891	64	24	с	2	35	30	ო	4	27	с	-	-	59	ı	ī	ı	ī	ī	ī	ī	ī
Kolodziejczak	0.906	299	47	28	0	224	196	0	2	98	28	0	21	250	0	0	2	297	ī	ī	ī	·
Low	0.842	19	1	2	0	9	2	0	0	17	ī	ī	ī	ī	2	0	0	17	-	0	с	15
Mantoo	0.941	68	26	0	7	40	40	2	0	26	ī	ī	ī	ī	ī	ī	ı	ī	ī	ī	ī	ī
West	0.810	21	0	-	-	19	18	-	-	-	ı	ı	ı	ı	ı	ı	ı	ı	ı	ı	ı	ı

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Figure 2. Quality-2 assessment using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) tool.

Heterogeneity Test and Pooled Analysis Results: A high degree of heterogeneity was found between the studies ($I^2=72.1\%$, P = .000), indicating a large degree of heterogeneity in the data between the 12 original studies; therefore, a REM was used for summary analysis. The metamerge analysis showed the accuracy of 3D-EAUS in the diagnosis of anal fistula as ES: 91% (95% CI, 88-94%) (Figure 3).

Subgroup Analysis: Three studies^{11,17,18,20,21} were from Asia, several studies^{12,13,15,19,22,23} were from Europe, and we performed a subgroup analysis by region. The heterogeneity of each group was as follows: Asian group ($l^2 = 78.5\%$, P = .001), European group ($l^2 = 58.9\%$, P = .024), and total ($l^2 = 72.1\%$, P = .000), indicating wide heterogeneity.

One study¹¹ used the Olympus RU-75M ultrasonic diagnostic system, several studies¹²⁻²² used the BK Medical ultrasound system. The subgroup analysis was conducted using ultrasound instruments as the classification, and the results are shown in Figure 4.



Figure 3. Forest plot of the diagnostic accuracy of fistula type using 3D-EAUS.

The Olympus group contained only 1 original study, therefore there was no heterogeneity. There was a certain degree of heterogeneity in the BK Medical group ($l^2 = 43.9\%$, P = .058). The results of the meta-analysis

were: Olympus group ES: 71% (95% Cl, 62-81%); BK Medical group ES: 93 % (95% Cl 91-96%); and total ES: 91% (95% Cl 88-94%).

Study ID		ES (95% CI)	% Weight
Olympus			
Almeida, I S		0.71 (0.62, 0.81)	6.61
Subtotal (I-squared = .%, p = .)	\diamond	0.71 (0.62, 0.81)	6.61
BK Medical			
Brillantino, A		0.94 (0.91, 0.97)	12.94
Brillantino, A		 0.98 (0.95, 1.00) 	13.45
Buchanan, G N	-	- 0.90 (0.78, 1.03)	4.70
Garces, Albir M	-	► 0.93 (0.84, 1.02)	6.83
Garces, Albir M	+	► 0.93 (0.87, 0.99)	9.84
Ghafoori, M	-	► 0.94 (0.87, 1.02)	8.16
Kim, Y	-	- 0.89 (0.81, 0.97)	8.20
Kolodziejczak, M	•	0.91 (0.87, 0.94)	12.75
Low, S F		- 0.84 (0.68, 1.01)	3.17
Mantoo, S	÷	0.94 (0.88, 1.00)	10.29
West, R L		- 0.81 (0.64, 0.98)	3.06
Subtotal (I-squared = 43.9%, p = 0.058)	(0.93 (0.91, 0.96)	93.39
Overall (I-squared = 72.1%, p = 0.000)	¢	0.91 (0.88, 0.94)	100.00
NOTE: Weights are from random effects an	alysis		
-1.03 0)	1.03	

Figure 4. Forest plot of the accuracy of different 3D-EAUS ultrasound instruments for diagnosis of fistula type.



Figure 5. Analysis of 3D-EAUS sensitivity for fistula type accuracy.

Sensitivity Analysis and Publication Bias: After excluding the studies one by one, meta-analysis was performed on the remaining studies. The changes in sensitivity and specificity found to be were small (<5%), and the stability of the included studies was good, as shown in Figure 5.

Using the Stata software for Begg's test, Z = 1.99, P = .047 (P < .05), the difference was found to be statistically significant, and it was considered that the 12 articles included had a publication bias.

Due to publication bias, metatrim was used for analysis. Using the linear method, after 2 iterations, the number of missing studies was estimated to be 0. After re-analyzing all studies, it was determined that ES: 92.7% (95% CI, 92.5-93.0%), the results were not significantly different, indicating a stable outcome.

Anal Fistula Internal Openings

Heterogeneity and Results of the Meta-analysis: Several studies^{12-16,18,20-22} contained data on internal openings, and combined heterogeneity analysis of sensitivity heterogeneity ($I^2 = 66.85\%$, P = .000) and specificity heterogeneity ($I^2 = 10.43\%$, P = .35) indicated that there was still a certain degree of heterogeneity; therefore, the REM was chosen. Meta-analysis showed that the sensitivity and specificity were 97% (95% CI, 93-99%) and 61% (95% CI, 42-76%), as shown in Figure 6.







Figure 7. 3D-EAUS diagnostic SROC curve for anal fistula.

SROC Curve: SROC curves were plotted, and the AUC was calculated to be 0.86 (95% CI, 0.83-0.89), as shown in Figure 7.

Sensitivity Analysis: After excluding the included studies one by one, meta-analysis was performed on the remaining studies. The changes in sensitivity and specificity were found to be small (<5%), and the stability of the included studies was good.

Analysis of Various Types of Anal Fistula: A meta-analysis of intersphincteric fistula, transsphincteric fistula, and suprasphincteric fistula was carried out. When the heterogeneity was large, the REM was used for the summary analysis. When the heterogeneity was small, the fixed effects model was used for the summary analysis. The subgroup analysis was conducted using ultrasound instruments as the classification, and the results are shown in Tables 3 and 4.

Pooled Analysis Results and Sensitivity Analysis: 3D-EAUS has high sensitivity and specificity for intersphincteric fistula, transsphincteric fistula, and suprasphincteric fistula. Among them, the transsphincteric fistula has the highest sensitivity of 95%, and the suprasphincteric fistula has the highest specificity of 99%.

For surgery, the wrong classification may lead to wrong preoperative assessment and poor prognosis. Therefore, the hazards of missed diagnosis rate and misdiagnosis rate are equally significant. The Youden index can be used to comprehensively evaluate the diagnostic accuracy of 3D-EAUS for different types of anal fistula. After calculation, the Youden indices of transsphincteric fistula, intersphincteric fistula, and suprasphincteric fistula were 0.80, 0.84, and 0.68 respectively.

Sensitivity analysis was performed on different types of anal fistula. The changes in sensitivity and specificity were small (<5%).

Table 3. 3D-EAUS Sensitivity and Specificity for Various Types of Anal Fistula Meta-analysis

	Intersphinc	teric Fistula	Transsphine	cteric Fistula	Suprasphine	teric Fistula
	ES (95% CI)	SP (95% CI)	ES (95% CI)	SP (95% CI)	ES (95% CI)	SP (95% CI)
Summary	85% (68-93%)	95% (90-97%)	95% (91-98%)	89% (76-95%)	68% (40-87%)	99% (98-99%)
Olympus	39% (20-62%)	90% (80-95%)	87% (76-93%)	52% (33-70%)	14% (8-76%)	98% (92-99%)
BK Medical	88% (76-94%)	96% (91-98%)	96% (92-98%)	91% (82-95%)	61% (49-72%)	99% (98-99%)

Table 4. 3D-EAUS Meta-analysis Heterogeneity of Various Types of Anal Fistula

	Intersphine	teric Fistula	Transsphin	cteric Fistula	Suprasphine	teric Fistula
	ES I ²	SP I ²	ES I ²	SP I ²	ES I ²	SP I ²
Summary	72.40%	52.00%	54.30%	74.50%	0.00%	0.00%
Olympus	-	-	-	-	-	-
BK Medical	52.30%	56.00%	39.10%	54.00%	0.00%	0.00%

Extrasphincteric Fistula and Superficial Fistula

Only 4 of the 12 studies included extrasphincteric fistulas, which were comprised of 8 cases. Ultrasound incorrectly defined 2 cases of extrasphincteric fistulas as other types, and incorrectly defined 1 case of another type of fistula as extrasphincteric fistula.

Only 5 of the 12 studies included superficial fistulas, including 19 cases. 3D-EAUS incorrectly defined 9 cases as other types.

DISCUSSION

Innovation

Muhammed RS Siddiqui conducted a meta-analysis of the diagnostic accuracy of transrectal two-dimensional ultrasound and MRI for anal fistula. Due to the earlier publication period, only 4 studies were included and the heterogeneity was high. Therefore, it is impossible to draw any reliable conclusions that could be used in clinical practice. However, the authors found that although MRI is more specific than EAUS, MRI and 2D-EAUS are quite sensitive in detecting anal fistula.²⁴ Marina Garcés Albir¹⁵ believes that 3D-EAUS is superior to 2D-EAUS in the diagnosis of anal fistula. However, there is currently no meta-analysis of the diagnostic accuracy of 3D-EAUS for anal fistula, and we conducted this study to fill this gap.

Heterogeneity

This study is a meta-analysis of the diagnostic accuracy of 12 3D-EAUS studies on anal fistula. The meta-analysis was conducted using the single-group rate model and the diagnostic test model. Since heterogeneity was unavoidable, and the heterogeneity was high, a REM was used for data analysis. After a subgroup analysis, we found that differences in the models of ultrasound instruments used were the main reason for the heterogeneity, and the secondary reasons may have been the different basic conditions of the research objects of each study and the differences in the experience levels of the doctors performing ultrasound examinations in each study. In addition, the study¹¹ only includes the South Asian population. Previous studies have shown that compared with other Asian and Western populations, the average thickness of the South Asian people's internal and external anal sphincter is smaller,²⁵ which may be a cause of heterogeneity.

Sensitivity Analysis and Publication Bias

When the 12 studies selected for this study were tested, the changes in sensitivity and specificity were small (<5%), and the stability was good. According to the

Begg's test, these 12 articles are currently considered to be biased for publication. However, after metatrim analysis, the results have not been found significantly different, indicating that the outcome is stable.

META-ANALYSIS DISCUSSION

The meta-analysis data show that 3D-EAUS has a high diagnostic value for anal fistula classification, with a total accuracy rate of 91%; it has high sensitivity and specificity for different anal fistula classifications, including transsphincteric fistula and intersphincteric fistula. However, it has low diagnostic accuracy for suprasphincteric fistula, and the Youden index is only 0.63. The reason may be that the transrectal three-dimensional probe can only clearly show the structure within 10 cm from the anal margin. Three-dimensional scanning is difficult to perform when the anal fistula is too deep.

Due to the low incidence of extrasphincteric fistula and superficial fistula, the 1057 cases of anal fistula only contained 8 cases and 19 cases respectively, and metaanalysis could not be performed. 3D-EAUS is not highly diagnostic for these 2 types of anal fistula. The reason may be that the external sphincter fistula is located far from the rectal cavity. The 3D-EAUS probe is a highfrequency probe, and it shows a reduction in the clarity of deep lesions.⁷ Another reason is that the incidence of these 2 types is low, and if the experience of doctors performing ultrasound examination is relatively inadequate, it is easy to misdiagnose these 2 types. Due to the small number of included cases, it is currently impossible to truly show the diagnostic accuracy of 3D-EAUS for these 2 types.

3D-EAUS has higher sensitivity and lower specificity for the diagnosis of the internal opening of anal fistulas—the sensitivity and specificity are 97% and 61%, respectively. The area under the SROC curve of this study is 0.86, indicating that 3D-EAUS is highly diagnostic for the internal opening of the anal fistula. The reason for the high sensitivity may be that the internal opening of the anal fistula is closer to the probe, which can be clearly displayed by the 3D-EAUS probe. The reason for the low specificity may be that some of the included anal fistula patients are cases of relapse. With 3D-EAUS, it is easy to mistake the previous surgical scar as an internal anal fistula.⁴

Study Limitations

The shortcomings of this study were: (1) literatures other than those in English were not included, which may

have caused bias; (2) the age and sex composition of the patients included in the selected research institutes were different; (3) the number of cases in some documents was insufficient; (4) the research included a small number of studies, and the analysis of heterogeneous sources could not be further explored; (5) the proficiency and experience level of the operator could also have had a certain impact on the results; and (6) Begg's test indicated that there was publication bias in the included studies.

CONCLUSION

In summary, 3D-EAUS can be used as the first-line diagnostic tool for anal fistula, because it has a high diagnostic accuracy for most anal fistulas, and has the advantages of simplicity, non-invasiveness, and good repeatability. However, due to the insufficient diagnostic accuracy of 3D-EAUS for complex fistulas, 3D-EAUS combined with MRI examination can be used to more accurately detect the secondary extension of complex fistulas, so as to describe the complete anatomy of the fistula in more detail.

Ethics Committee Approval: This study was approved by the Institutional Review Board of our institution.

Informed Consent: The requirement for informed consent was waived due to the retrospective nature of this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – J.L., S.N.C.; Design – J.L.; Supervision – S.D.Q.; Resource – F.C.; Materials – J.L., S.N.C.; Data Collection and/ or Processing – J.L., S.N.C., Y.Y.L., Z.M.Z., D.L.Y.; Analysis and/or Interpretation – J.L., S.N.; Literature Search – J.L., S.N.C., Y.Y.L., Z.M.Z.; Writing – J.L., S.N.C.; Critical Reviews – F.C., S.D.Q.

Conflict of Interest: The authors have no conflict of interest to declare.

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