Fistula plug versus conventional surgical treatment for anal fistulas

A system review and meta-analysis

Yu-Wei Pu, *MD,* ***Chun-Gen Xing,*** *PhD,* ***Imran Khan,*** *MD,* ***Kui Zhao,*** *MD,* ***Bao-Song Zhu,*** *MD,* ***Yong Wu,*** *MD.*

ABSTRACT

الأهداف: تقييم تكرارسلس البراز لقابس الناسور الشرجي بالمقابل مع العلاج الجراحي التقليدي للناسور الشرجي.

الطريقة: أجريت دراسة تحليلية في قسم الجراحة العامة، مستشفى سوتشو الثاني التابع لجامعة سوتشو، الصين. قمنا بالبحث في قواعد البيانات الطبية ومكتبة كوكرين خلال الفترة من يونيو 2011م حتى أبريل 2012م. أجريت عملية البحث باستخدام المواضيع الطبية والكلمات الطبية مثل الناسور الشرجي، لاصقة الفبرين، تسرب الفبرين، وقابس الفبرين.

النتائج: شملت هذه الدارسة على على دراستين عشوائيتين و٣ دراسات استرجاعية وضمت على ٤٢٨ مريض. كان معدل النكسةعاليا لدى المرضى الذين خضعوا للعلاج بقابس الناسور (62.1% مقابل 47%) (p=0.004).

خاتمة: حقق علاج قابض الناسور الشرجي قبولا مرضيا مع خطورة أقل لحدوث سلسل البراز ولكن معدل النكسة عالي بشكل إحصائي بالمقارنة مع العلاج الجراحي التقليدي. كما أنه أقل غزوا، وتكرارا،واستبقاءالمصرة. ولكن خففت هذه الدراسة في الحصول على اختلاف إحصائي مهم في معدل النكسة بالإصابة بسلس البراز بالمقارنة مع العلاج التقليدي الجراحي.

Objectives: To evaluate the recurrence and fecal incontinence of anal fistula plug versus conventional surgical treatment for anal fistulas.

Methods: This meta-analysis was carried out in the General Surgery Department of the Second Affiliated Hospital of Soochow University, Suzhou, Jiangsu Province, China. We searched the Medline, EMBASE, and the Cochrane Library from June 2011 to April 2012. The literature searches were carries out using medical subject headings and free-text word: anal fistula, fibrin adhesive, fibrin sealant, and fistula plug.

Results: Two randomized controlled trials and 3 retrospective controlled studies were included. A total of 428 patients were included in our study. The recurrence rate was higher in those patients who accept fistula plug treatment (62.1% versus 47%) (p=0.004).

Conclusion: Anal fistula plug has a moderate probability of success with little risk of incontinence, but the recurrence rate is significantly higher than the conventional surgical treatment. This treatment is minimally invasive, repeatable, and sphincter-sparing. This meta-analysis failed to find a statistically significant difference in incontinence rate between conservative treatment and conventional surgical treatment.

Saudi Med J 2012; Vol. 33 (9): 962-966

From the Department of General Surgery, The Second Affiliated Hospital, Soochow University, Suzhou, Jiangsu Province, China.

Received 16th April 2012. Accepted 5th August 2012.

Address correspondence and reprint request to: Dr. Chun-Gen Xing, Department of General Surgery, The Second Affiliated Hospital, Soochow University, Suzhou 215006, Jiangsu Province, China. Tel. +86 (512) 67784106. Fax. +86 (512) 67784106. E-mail: xingcg@126.com

In the last 2 decades, sphincter preserving methods have been developed. Fibrin glue and fistula plug are methods with excellent functional outcomes, and no evidence of fecal incontinence, but the success rates have decreased in recent years.[1,2] The advancement mucosal flap is the gold standard with a high success rate ranges from 63-95.4%,[3-6] but with a risk of fecal incontinence (9-52%).[3,4,6] The recurrence rates found in the literature for the anal fistula plug vary range from 13.9-90.6%[7-20] (**Table 1**) and from 40-86%[21-24] for fibrin

glue. The aim of this study is to evaluate the recurrence and fecal incontinence of anal fistula plug (AFP) versus conventional surgical treatment for anal fistulas.

Methods. This meta-analysis was carried out from June 2011 to April 2012 in the General Surgery Department of the Second Affiliated Hospital of Soochow University, Suzhou, Jiangsu Province, China. We searched the Medline (from 1966 to November 31, 2011), EMBASE (from 1980 to November 31, 2011) and, Cochrane Library (November 31, 2011). The literature searches were carried out using medical subject headings and free-text word: "anal fistula"; "rectal fistula"; "fibrin adhesive"; "fibrin glue"; "fibrin sealant", "fistula plug". Language is limited to English. Randomized controlled trials (RCT), cohort studies and retrospective clinical controlled trials comparing anal fistula plug versus conventional surgical treatment in patients with anal fistula were used to do a search strategy. We used Review Manager 5.0 to conduct the review. The Mantel-Haenszel method was used for the statistical analysis. Dichotomous data were analyzed for odds ratio (OR) and 95% effectiveness confidence interval. The results were displayed by forest plot graph.

Inclusion criteria. All randomized, non-randomized controlled clinical trials, which compared fistula plug with conventional surgical treatment methods for anal fistula, and which reported clinical healing and incontinence of the fistula as the outcome, were included.

Exclusion criteria. Abstracts, letters, case reports, comments, and conference proceedings were not included in the review. Studies on patients with recto-vaginal fistula, rectal fistula, Crohn's disease or infected with HIV who were treated by fistula plug and patients undergoing additional procedure along with fistula plug were also excluded from the study. Studies reported patients with anal fistula treated with fibrin glue or fibrin sealant were also excluded.

Data collection. Two reviewers independently extracted the following from each study: first author, publication data, study design, inclusion criteria, and exclusion criteria. Both published and unpublished data were considered in this study.

Results. There are 2 RCTs[7,25] and 3 retrospective studies[8,26,27] with patients comparing anal fistula plug versus conventional surgical treatment (**Table 2**). In our statistic analysis, the recurrence rate is higher in the patients who underwent fistula plug treatment (82/132, 62.12%) versus conventional surgical treatment (139/296, 46.96%) (5 trials, 428 patients; p=0.004, OR: 1.91 [95% CI: 1.23- 2.97]) and there is a heterogeneity (Chi^2 = 15.73; I^2 =75%). The incontinence rate is obvious lower in those patients underwent fistula plug treatment (1/30, 3.33%) versus conventional surgical treatment (12/43, 27.90%), but it has no statistically significant (one trial, 73 patients; p=0.07; OR: 1.46 [95% CI: 0.97- 2.19]) (Chi^2 = 23.54, I^2 = 79%) (**Figure 1**).

We performed 2 subgroups analysis. The first analysis was for RCTs alone. The results of the subgroup analysis of RCTs alone are statistically significant (2 trials, 91 patients; p=0.001, OR: 4.32 [95% CI: 1.80-10.34]) (Chi^2 = 4.92, I^2 = 80%) (**Figure 2**). The second subgroup analysis of complex anal fistula is not statistically significant (2 trials, 240 patients; p=0.41, OR: 1.32 [95% CI: 0.68-2.56]) (Chi^2 = 12.75, I^2 = 92%) (**Figure 3**).

Discussion. Most of patients with anal fistula, preservation of continence is of greater importance than the success rate of the technique used to manage their anal fistula.[28] The plug in anal fistula is simple, safe, and the injections can be repeatable to increase the healing

Table 1 - Healing rate after fistula plug treatment for fistula-ano found in the literature.

Authors	Year	Patients	Healing rate (%)
Champagne et al[9]	2006	46 patients with high cryptoglandular anorectal fistulas	85.0
van Koperen et al[7]	2011	17 patients with complex high and recurrent fistulas	41.0
Schwander et al[10]	2008	19 patients with transsphincteric anorectal fistulas	45.5
Laws et al[11]	2008	20 patients with anal fistula	24.0
Christoforidis et al[8]	2008	47 patients with complex anal fistulas	43.0
Garg[12]	2009	23 patients with high cryptoglandular fistula-in-ano	71.4
Safar et al[13]	2009	35 patients with complex fistulas	13.9
Itah et al[14]	2009	10 patients with complex fistulas	50.0
Schwander et al[15]	2009	60 patients with single transsphincteric anorectal fistulas	62.0
Zubaidi & Al-Obeed[16]	2009	22 patients with anal fistula	83.0
Ellis et al[17]	2010	63 patients with anal fistula	81.0
Lenise et al[18]	2010	60 patients with cryptoglandular fistulae	90.6
Owen et al[19]	2010	32 patients with complex fistulas	37.0

Table 2 - Summary of published information on retrospective controlled study with their treatment.

Authors	Year	Type of study	Patients	Treatment
Ortiz et al[25]	2009	RCT	31 high transsphincteric fistula-in-ano	15 AFP versus 16 endorectal advancement flap
van Koperen et al[7]	2011	RCT	60 perianal fistula	31 fistula plug versus 29 mucosal advancement flap
Chung et al[26]	2009	RCT	232 anal fistula	27 fistula plug, 23 fibrin glue, 86 seton drain, 96 flap advancement
Christofordis et al[8]	2009	RCT	80 anal fistula	37 fistula versus 43 flap advancement
Jennifer et al[27]	2009	RCT	55 transsphincteric fistula	29 fistula plug versus 26 flap advancement

RCT - retrospective controlled study, AFP - anal fistula plug

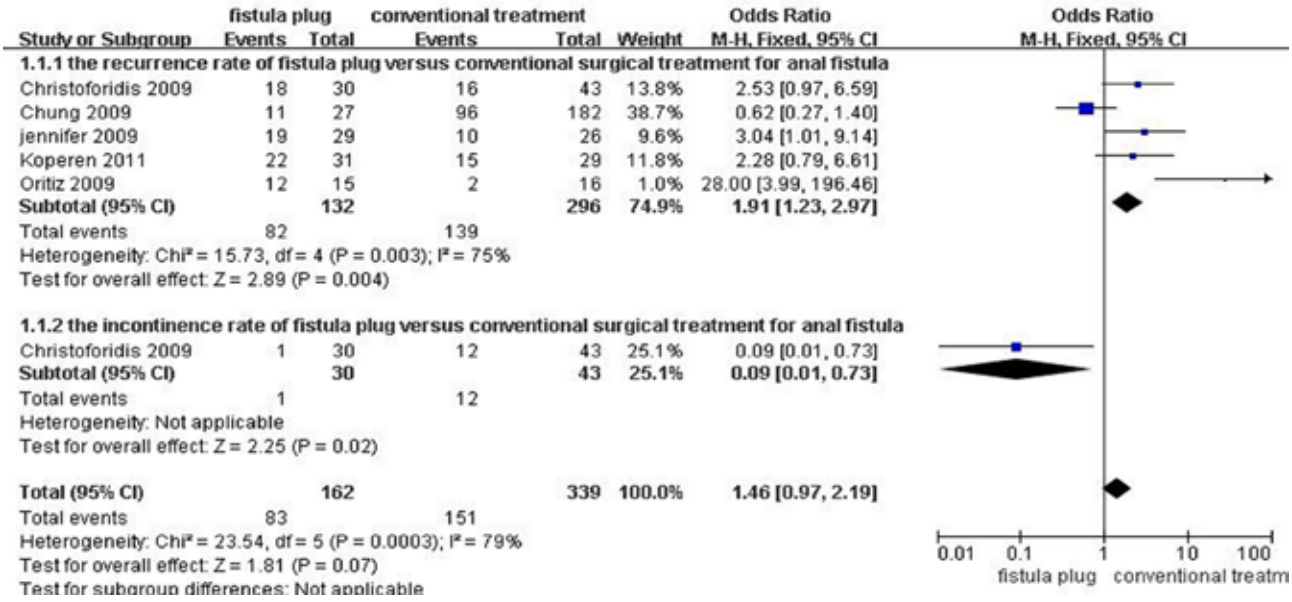

Figure 1 - Analysis of controlled studies of fistula plug versus conventional surgical treatment in patients with anal fistula. Outcome: 1.1 recurrence rate and 1.2 incontinence. 95% CI - 95% confidence interval, M-H - Mantel-Haenszel, df - degrees of freedom

rate. But the true rate of fistula healing is still uncertain and controversial. The recurrence rates found in the literature for the anal fistula plug vary range from 13.9-90.6%[7-20] (**Table 1**) and from 40-86%[21-24] for fibrin glue. Thus, we still not got a final conclusion on the true value of treatment with fistula plug treatment. Our statistical analysis confirm the poor long-term results in the patients who underwent plug rather than conventional surgical treatment, considering the recurrence rate (62.12% versus 47%) (OR 1.94, 95% CI: 1.23-2.97) after 12 weeks follow up. Only one study reported the incontinence rate that no difference between the 2 groups: 1/30 in the plug group (3.3%) versus 12/43 in the conventional surgical treatment (27.9%) (**Figure 1**).

Fistulotomy was most commonly used mode of management. The specific technique depends on the height of fistula in relation to the sphincteric mechanism. Fistulotomy are excellent, but there is some risk of anal incontinence. The advancement mucosal flap is the treatment with low recurrence rate, even one study reported 95.4% success rate,[4] but some studies reported 52% rate of fecal incontinence.[3,4] The success rate of both fistulotomy and advancement mucosal flap techniques decreases with time. Recurrence appears to be caused by failure of treatment and by recurrent patient disease.[5] Tract length predicts successful closure with anal fistula. Shorter fistulae tend to recur more than longer fistula, with rate of 61% versus 21%.[29] The shorter fistulae do not hold the plug that leads to plug extraction as well as the longer-tract fistula can hold. The present study shows that the plug is cost-effective for complex anal fistulas compared to the advancement mucosal flap. On average, option for the plug instead of the advancement mucosal flap could save $1,588

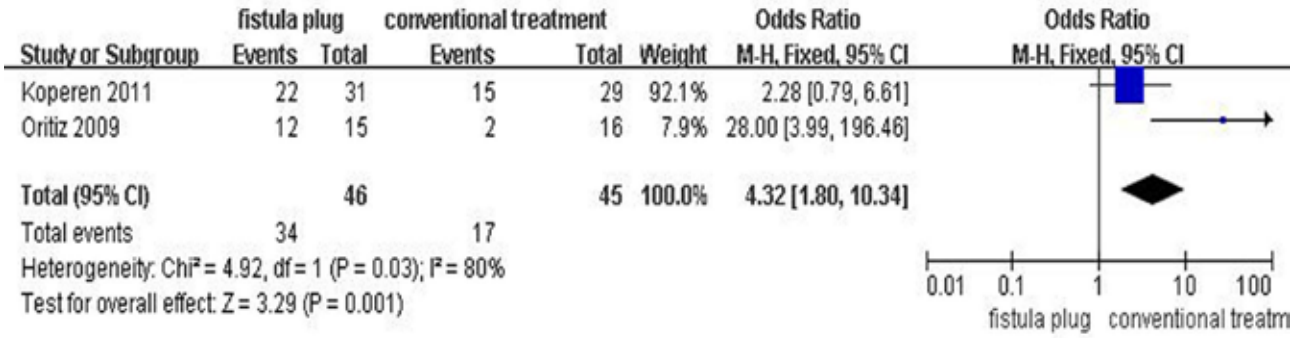

Figure 2 - Sub-group analysis of retrospective controlled studies (RCT) of fistula plug versus conventional surgical treatment in patients with anal fistula. Outcome: 1.1 recurrence rate. 95% CI - 95% confidence interval, M-H - Mantel-Haenszel, df - degrees of freedom

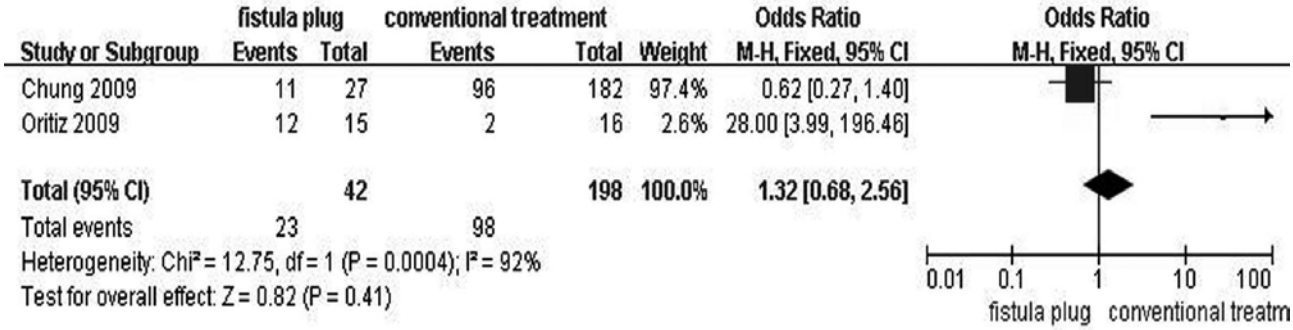

Figure 3 - Sub-group analysis of studies with complex anal fistula of fistula plug versus conventional surgical treatment. Outcome: 1.1 recurrence rate. 95% CI - 95% confidence interval, M-H - Mantel-Haenszel, df - degrees of freedom

per healed fistula. Hence, the plug may improve the long-term results and reduce healthcare costs when used as a first-line treatment for anal fistulas.[30]

Study limitation. The main limitation of our study is the little number of randomized controlled studies and we included some retrospective studies into the statistical analysis. When we searched the databases, we limited the language, we cannot find studies with the other language about our study.

In conclusion, the conventional surgical treatment is still the first choice for anal fistulas. The plug treatment is minimally invasive, repeatable, sphincter-sparing, and cost-effective. For the reason above mentioned, plug could be considered as the one choice, particularly in patients with poor anal sphincter function or with a high surgical risk. But both of the patients and doctors should be aware of the high recurrence rate.

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