

ORIGINAL ARTICLE**EVALUATION OF COMMUNITY-BASED TRICHIASIS SURGERY IN NORTHWEST ETHIOPIA**

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ABSTRACT

BACKGROUND: Surgery to correct trichomatous trichiasis (TT) is recommended to prevent blindness caused by trachoma. This study evaluated the outcomes of community-based trichiasis surgery with absorbable sutures, conducted in Amhara Regional State, Ethiopia.

METHODS: A simple random sample of 431 patients was selected from surgical campaign records of which 363 (84.2%) were traced and enrolled into the study. Participants were interviewed and examined for trichiasis recurrence, complications of TT surgery and corneal opacity. Multilevel logistic regression models were used to explore the associations between trichiasis recurrence, corneal opacity and explanatory variables at the eye level.

RESULTS: The prevalence of trichiasis recurrence was 9.4% (95% Confidence Interval [CI] 6.6-12.8) and corneal opacity was found in 14.3% (95% CI 10.9-18.3) of the study participants. The proportion of participants with complications of TT surgery was: granuloma 0.6% (95% CI 0.1-2.0); lid closure defects 5.5% (95% CI 3.4-8.4) and lid notching 16.8% (95% CI 13.1-21.1). No factors were identified for trichiasis recurrence. Corneal opacity was associated with increased age ($P_{trend}=0.001$), more than 12 months post surgery (OR=2.7; 95%CI 1.3-5.6), trichiasis surgery complications (OR=2.9; 95%CI 1.4-5.9) and trichiasis recurrence (OR=2.5; 95%CI 1.0-6.3).

CONCLUSION: Prevalence of recurrent trichiasis and granuloma were lower than expected but higher for lid closure defects and lid notching. The majority of the participants reported satisfaction with the trichiasis surgery they had undergone. The findings suggest that recurrence of trichiasis impacts on the patients' risk of developing corneal opacity but longitudinal studies are required to confirm this.

KEY WORDS: Corneal opacity, Trichiasis, Trichiasis recurrence, Ethiopia

INTRODUCTION

Trachoma, a treatable disease caused by *Chlamydia trachomatis*, is the most common infectious cause of blindness worldwide. It is estimated that there are 40 million people with active trachoma and 8.2 million with trichiasis (1).

In 1998, the World Health Assembly passed a resolution to eliminate blinding trachoma by the

year 2020 (2). The recommended strategy for trachoma control is "SAFE": S standing for Surgery to correct trichomatous trichiasis, A for Antibiotics, F for Facial cleanliness and E for Environmental improvements (3). The two most disabling sequelae of trachoma are trichiasis and corneal opacity. The surgical component of the programme is, therefore, critical in preventing of blindness in patients with trichiasis.

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The priority of health care in developing countries focuses on communicable diseases which are

Ethiopia has the largest burden of trachoma in the world with approximately 10 million cases of active disease and 1.2 million cases of trachomatous trichiasis (TT) (4,5). To address the backlog of patients in need of surgery for TT, high volume, community-based eye surgery camps were conducted in addition to surgery performed at health centres. Surgery (transverse tarsotomy and lid rotation) was performed by Integrated Eye Care Workers (IECWs). As patient follow-up has proved difficult in rural areas, absorbable sutures were used.

Reported post-operative recurrence rates of trichiasis vary from 11% to 62% depending on the length of follow-up and the location of the study. However, most results come from programmes in which patients were regularly followed up and none described the use of absorbable sutures. Potential risk factors for trichiasis recurrence that have been identified include: severity of trichiasis prior to surgery (6-10), increasing age (11-13), previous surgery (14,15), chlamydial infection (16), surgeon (13,17), and residence in a high risk area (18,19).

Few studies have assessed the prevalence of postoperative complications. Prevalence of granulomas varied from 10.5% (20) to 15% (21), lid notching from 1.2% (22) to 6.3% (23) and defective lid closure from 1.3% (24) to 3.9% (25). One study found out surgeon to be predictive of granuloma formation and eyelid closure defects, but baseline trichiasis severity predictive of eyelid contour abnormalities (26).

In one study (27), surgical correction of trichiasis resulted in a lower prevalence of corneal opacity suggesting that some corneal recovery can occur. The majority of eyes that developed corneal opacity had recurrent trichiasis but a few did not, suggesting that causal mechanisms other than recurrence of trichiasis, also play a part in damaging the cornea. So far, no study has looked at the impact of trichiasis recurrence and/or post-operative complications on the development of corneal opacity and consequent blindness.

There is currently no system for follow-up of patients undergoing surgery for TT in Amhara Regional State, Ethiopia due to the cost and practical difficulties that this would incur. This study primarily aimed to investigate the

prevalence of trichiasis recurrence, complications and corneal opacity, following community-based surgery using absorbable sutures. Secondly, the study aimed to explore risk factors associated with outcomes of trichiasis surgery and assesses patients' attitudes to trichiasis surgery.

PATIENTS AND METHODS

Study population and design: This cross-sectional study was conducted in four *Woredas* (districts) of Amhara Regional State in Ethiopia: Jabi Tehnan, Hulet Eju Enese, Estie and Bahar Dar Zuria, in September and October 2006. It was estimated that a sample of 430 patients would be required to detect an estimated prevalence of granuloma of 10% with a precision of 3% at 5% level of significance and power of 90%, allowing for 20% of patients to be untraceable.

The sampling frame was comprised of approximately 5,000 patients who had undergone TT surgery in eye camps between October 2005 and August 2006. TT surgery logs from different surgeons in the target districts were collected to generate a line list of all patients, including patient identifiers and addresses. Individuals who had surgery at one of the camps but were not residents of the *woreda* of interest were excluded from the study due to difficulties in tracing them. Patients on the generated list were assigned computer generated random numbers and then sorted in ascending order of the numbers. Study participants were selected by taking the first 430 patients on the random number ordered list.

Data collection: Assessments were performed by experienced Integrated Eye Care Workers (IECWs) who had not performed surgery on any of the participants and were blinded to which a surgeon had conducted the surgery. The IECWs underwent three days of theoretical and practical training, offered by an ophthalmic surgeon and a public health specialist, on how to complete the study questionnaire and perform the clinical examination. Participants were located using the home addresses recorded in the TT surgery register and with the help of the local administration. Verbal informed consent was

obtained from all participants prior to enrolment in the study.

Interviews: Each participant was interviewed using a structured questionnaire. Questions were designed to ascertain demographic information, history of epilation, attitudes towards surgery and complications experienced following surgery. The questionnaire was translated from English into Amharic and piloted on ten patients in prior to commencement of the study. Interviews were conducted by IECWs in Amharic. Completed forms were verified in the field immediately after the interview by a trachoma programme supervisor. Any missing responses or incorrectly-followed skip patterns were rectified immediately.

Eye examination: Eye examination was performed on each participant using a torch and x2.5 magnifying loupes. For every patient both eyes were examined separately and the findings for the eyes that had been operated recorded. If any abnormalities were diagnosed (in either eye whether or not that eye had been operated on), the individual was referred for eye care according to national guidelines.

Data entry and analysis: Each form was assigned a unique serial number and data were double-entered by different data entry clerks using EPI Info (Centers for Disease Control and Prevention [<http://www.cdc.gov/EpiInfo>])). The data was validated and cleaned and personal identifiers removed before electronic data sets were exported for analysis. The data were analysed using StataTM 9 version (Stata Corporation, College Station, Texas). Three key outcomes of interest were examined: trichiasis recurrence; complications of trichiasis surgery; and corneal opacity.

The demographic characteristics of the participants were explored using cross-tabulations. Percentage proportions were used to describe the prevalence and distributions of data by specified categories. Differences in proportions were investigated using chi-squared tests. Since the study population was a simple random sample 95% confidence, intervals of the prevalence estimates were derived using the binomial exact method.

Eye level analysis was performed to investigate associations between potential risk factors and outcomes of interest. In order to take

account of the fact that the outcome for each eye was not independent, Generalised Linear Latent and Mixed Models (GLLAMMs) were used to examine risk factors accounting for non-independence of eyes at patient level (28). Univariate analysis was conducted for each potentially explanatory risk factor for each outcome of interest (trichiasis recurrence and corneal opacity). Multivariable models were then developed by stepwise regression analysis for model selection using a 5% significance level for inclusion/ exclusion of variables from the model based on likelihood ratio test. Age and sex were retained in all multivariable models to control for potential confounding effects.

This evaluation was a routine public health practice to inform implementation of SAFE interventions. We used verbal informed consent which is routine practice during surveys undertaken by National Trachoma Control Programs. The Institutional Review Board of Emory University (IRB # 221) and the Amhara Regional Health Bureau approved the study protocol and the verbal consent procedures. The purpose of the study was explained in detail to each participant in the local language, i.e. Amharic. Verbal informed consent to participate in the study was obtained from each participant and guardians of minors in accordance with the declaration of Helsinki. Consent for interviews and eye examination was documented by examiners on the data collection forms. Personal identifiers were removed from the data set before analyses were undertaken.

RESULTS

Characteristics of participants: Table 1 shows the characteristics of the study participants. A total of 431 people were sampled of whom 363 (84.2%) participated in the study. The majority of the participants (52.6%) were 41-60 years of age compared to 36.8% of those who were not traceable. Of the 68 non-participants, 33 had moved away from the village permanently, 24 had travelled away from the village temporarily, 6 were deceased and 5 untraceable. The mean (standard deviation) age of the study participants was 49.5 (13.4) years and the majority were females (66.9%). The operations were performed by fifteen different TT surgeons but

the majority of operations (over 70%) were performed by just four of these fifteen. The median number of patients operated on by each surgeon was 17 (interquartile range 6-27). A total of 233 patients (64.2%) were operated on

both eyes while the rest were operated on either the right (18.2%) or the left eye (17.6%). Therefore, 596 eyes were included in the eye level analysis.

Table 1: Characteristics of study participants (n=431)

Characteristic	Participated in study		Not traceable		Chi-square test	
	n	%	n	%		
Sex	Male	120	33.1	26	38.2	P=0.408
	Female	243	66.9	42	61.8	
Age in years	11-20	5	1.3	4	5.9	p=0.018
	21-30	16	4.4	6	8.8	
	31-40	58	16.0	12	17.6	
	41-50	89	24.5	17	25.0	
	51-60	102	28.1	8	11.8	
	61-70	61	16.8	12	17.6	
	71-80	27	7.4	6	8.8	
	81+	5	1.3	3	4.4	
Woreda	1 Jabi Tehnan	111	30.6	36	52.9	P≤0.001
	2 Hulet Eju Enese	78	21.5	17	25.0	
	3 Estie	31	8.5	7	10.3	
	4 Bahar Dar Zuria	143	39.4	8	11.8	
Education	Illiterate	332	91.4	n/a	n/a	
	Non formal education	22	6.1	n/a	n/a	
	Formal (primary or secondary) education	9	2.5	n/a	n/a	
Eyes operated	Right only	66	18.2	n/a	n/a	
	Left only	64	17.3	n/a	n/a	
	Both eyes	233	64.2	n/a	n/a	

n/a, data not available because patients were not interviewed or examined

Knowledge, attitudes and practices towards trichiasis and trichiasis surgery: Table 2 summarises the respondents' knowledge attitudes and practices of trichiasis and trichiasis surgery. Nearly two fifths (39.1%) of the participants reported that trichiasis and trachoma were connected and the majority of the participants (91.5%) reported that trachoma/trichiasis causes blindness. Epilation of eyelashes prior to surgery was carried out by 71.9% of the participants and nearly half (47.9%) reported epilating more than once a

week. Most of the participants reported having been advised to go for surgery by a health worker (29.2%) or by beneficiaries of TT surgery (29.8%). The majority of the participants reported improvement following TT surgery (98.1%), would undergo surgery again if required (96.7%) and would recommend surgery to others (97.2%). The main reasons for the perceived improvement were correction of the trichiasis (95.8%), relief from pain (97.2%) and improved vision (92.7%).

Table 2: Knowledge, attitudes and practice about trichiasis and trichiasis surgery

Particulars		Number of responses (%)
Knowledge	Trichiasis is connected with trachoma	142 (39.1)
	Trachoma/trichiasis can potentially lead to blindness	332 (91.5)
Practice prior to surgery	Epilation for trichiasis before the surgery	261 (71.9)
	Frequency of epilation \geq one week	125(47.9)
Advice to attend surgery	Trachoma volunteer	79(21.8)
	Health worker	106 (29.2)
	Family member	60 (16.5)
	Beneficiary of surgery	108 (29.8)
Attitude post surgery	Other	9 (2.5)
	Reported improvement following surgery	356 (98.1)
	Would undergo surgery again in case you need it	351 (96.7)
	Have you advised other trichiasis patients to seek surgery	353 (97.2)

Prevalence of trichiasis recurrence, complications of surgery and corneal opacity:

Table 3 summarises the prevalence of trichiasis and complications of trichiasis surgery at the eye level and at the patient level. Of the 363 participants enrolled into the study, recurrence of trichiasis after surgery occurred in 34

participants (9.4%, 95% Confidence Interval [CI] 6.6-12.8). Of the 34 participants with recurrence, seven (20.6%) had bilateral trichiasis. In total, 100 participants had an adverse outcome: 16.8% experienced lid notching, 5.5% had a lid closure defect and 0.6% developed granuloma (Table 3).

Table 3: Prevalence of adverse outcomes after surgery

Complication	Number of eyes (%)		Patients based on worst affected eye (N=363)		
	Right (N=299)	Left (N=297)	Number of patients	%	95% CI
Trichiasis	19 (6.4)	22 (7.4)	34	9.4	6.6-12.8
Granuloma	1 (0.3)	1 (0.3)	2	0.6	0.1-2.0
Lid closure defect	12 (4.0)	12 (4.0)	20	5.5	3.4-8.4
Over correction	2 (0.7)	2 (0.7)	4	1.1	0.3-2.8
Lid notching	44 (14.7)	27 (9.2)	61	16.8	13.1-21.1

CI = confidence interval

Factors associated with trichiasis recurrence and corneal opacity: A total of 596 eyes (in 363 patients) that had been operated were included in the risk factor analysis. From the multilevel

logistic regression analysis, no explanatory factors showed a statistically significant association with trichiasis recurrence (Table 4).

Table 4: Association of recurrence of trichiasis and potential risk factors, eye level analysis (n=596)

Risk factor		Total no of eyes	Eyes with TT recurrence	% TT recurrence	Univariate analysis			
					Odds Ratio	95% CI	P value	P value for trend
Sex	Male	188	16	8.5	1.0			
	Female	408	24	5.9	0.6	0.3-1.4	0.25	
Age	<45	197	10	5.1	1.0			0.11
	45-64	325	22	6.8	1.4	0.6-3.6	0.43	
	≥65	74	8	10.8	2.7	0.8-8.4	0.09	
Education	Illiterate	549	37	6.7	1.0			
	Non formal or formal education	47	3	6.4	0.8	0.2-3.6	0.80	
Time since trichiasis surgery	0-12 months	495	33	6.7	1.0			
	>12 months	101	7	6.9	0.9	0.3-2.4	0.85	
Epilation prior to surgery	Yes	442	34	7.7	1.0			
	No	154	6	3.9	0.4	0.1-1.2	0.17	
Frequency of epilation	Once a week or more	223	16	7.2	1.0			
	Less than once a week	218	18	8.3	1.6	0.7-3.9	0.30	
	Not at all	155	6	3.9	0.5	0.2-1.6	0.24	
Any surgical complication	No	511	33	6.5	1.0			
	Yes	85	7	8.2	1.2	0.5-3.1	0.72	

Association of corneal opacity and potential risk factors, eye level analysis: table 5 summarises the association of corneal opacity and explanatory factors. Corneal opacity was independently associated with increasing age ($P_{trend}=0.001$), surgery more than 12 months previously (OR=2.7, 95%CI 1.3-5.5), any surgical complication (OR=2.9, 95%CI 1.4-5.9) and trichiasis recurrence (OR=2.5, 95%CI 1.0-6.3).

DISCUSSION

The prevalence of trichiasis recurrence was low at 9.4% compared to other studies which have described prevalence ranging from 10.8%(29) to 61.8%(30). The prevalence of granuloma was also low at 0.6%. No definite conclusions can be drawn from this given that there was no comparison group in whom non-absorbable

sutures were used but such a low rate does suggest that the use of absorbable sutures does not increase the risk of granuloma after trichiasis surgery. The prevalence of overcorrection was very low at 0.5% but the rate of lid notching was much higher at 16.8%, while 5.5% of patients had a lid closure defect compared with rates of 1.2% for lid contour abnormalities and 1.3% for lid closure defects in another study (31). The latter is important to identify as an inability to close the lid fully over the cornea can lead to corneal damage secondary to exposure and consequent visual impairment. One in seven participants (14.3%) had corneal opacity at follow-up examination; however, we lack preoperative data for comparison.

This study was a cross-sectional survey of patients who had undergone trichiasis surgery. In this study, a simple random sample design

Table 5: Association of corneal opacity and potential risk factors, eye level analysis (n=596)

Risk factor		Total no of eyes	Eyes with corneal opacity	Percentage of eyes with corneal opacity	Univariate analysis				Multivariate analysis				
					Odds Ratio	95%CI	P-value	P-value for trend	Odds Ratio	95% CI	P value	P value for trend	
Sex	Male	188	29	15.4	1.0				1.0				
	Female	408	44	10.8	0.6	0.4-1.2	0.14		0.7	0.3-1.4	0.314		
Age	<45	197	12	6.1	1.0			<0.001	1.0				0.001
	45-64	325	43	13.2	2.8	1.3-6.3	0.01		3.0	1.3-6.6	0.008		
	≥65	74	18	24.3	5.5	2.2-13.7	<0.01		4.9	1.9-12.7	0.001		
Education	Illiterate	549	71	12.9	1.0								
	Non formal or formal education	47	2	4.3	0.2	0.04-1.1	0.06						
	Some formal	14	0	0.0									
Time since trichiasis surgery	0-12 months	495	54	10.9	1.0				1.0				
	>12 months	101	19	18.8	2.4	1.2-4.9	0.01		2.7	1.3-5.5	0.007		
Epilation prior to surgery	Yes	442	51	11.5	1.0								
	No	154	22	14.3	1.2	0.7-2.3	0.54						
Frequency of epilation	Once a week or more	223	21	9.4	1.0							0.24	
	< Once a week	218	30	13.8	1.6	0.8-3.1	0.20						
	Not at all	155	22	14.2	1.5	0.7-3.1	0.26						
Any surgical complication	No	511	54	10.6	1.0				1.0				
	Yes	85	19	22.4	2.5	1.3-4.7	0.01		2.9	1.4-5.9	<0.01		
Recurrence of trichiasis	No	556	63	11.3	1.0				1.0				
	Yes	40	10	25.0	2.7	1.1-6.4	0.03		2.5	1.0-6.3	0.042		

was used because it was possible to generate a sampling frame based on the TT surgical logs. This sampling approach is robust and prevents selection bias. Just over 15% of the sample was not traceable which was better than expected in this setting. However, there were differences in the age distribution and districts of residence among the participants and non-participants: compared to patients enrolled in the study, the non-participants were likely to be younger and resided in Jabi Tehnan district. While these differences are a potential source of bias, it is not possible to adjust for their effects. The majority of non-participants had moved away from the village or were travelling temporarily so we can hypothesise that they were less likely to have trichiasis recurrence, TT surgery complications and corneal opacity because of their younger age and ability to relocate. Other potential limitations with this study include a lack of baseline measurement of corneal opacity and severity of entropion prior to surgery that may influence TT recurrence(32) and corneal opacity (33). In addition, we did not collect data on if the surgery was the first or repeat surgery following recurrence of TT. It can be expected that patients undergoing TT surgery following recurrence are more likely to experience recurrence of TT and other complications. Nonetheless, since the SAFE strategy was being introduced in the study districts for the first time, we can expect that the majority of the participants were presented for the first TT surgery.

This study reflects very positively on the trachoma programme in Amhara Regional State in terms of the low rates of trichiasis recurrence and granuloma and high satisfaction with trichiasis surgery. It suggests that an appropriate type of trichiasis surgery is being used and that the use of absorbable sutures does not increase the incidence of granuloma. This is further supported by a recent randomized trial comparing outcomes of absorbable sutures and non-absorbable silk suture that showed no differences in trichiasis recurrence, surgical complications and corneal opacity (34). There was huge variability in the number of operations performed by each surgeon (range 1 to 93) in this sample. It would be helpful to know if this degree of variation is reflected in the

annual workload of individual surgeons or whether the surgeons who performed few operations in the eye camps did more surgeries in the health centres and vice versa. An alternative explanation could be that those who performed few operations were undergoing training at the time in which case one would expect their surgical results to differ from more experienced surgeons. In an evaluation of productivity of TT surgeons, Habtamu et al. found that TT surgeons who were retained in the programme were doing very few operations; therefore, they were unlikely to maintain their TT surgical skills (35).

Given that recurrence of trichiasis and other complications increase the risk of corneal opacity (which is what the programme is trying to prevent) and that patients who have a positive experience of surgery are the best ambassadors to their communities in terms of persuading others to come forward for surgery, maintaining a high surgical standard should be a priority. One of the major drawbacks of the current system is absence of any form of systematic follow-up after surgery. This means that there is a lack of accountability and feedback to each surgeon about the quality of the surgery that they are performing. It also presents a problem in terms of managing the quality of the programme overall and determining its sustainability.

The SAFE strategy works best when all interventions are implemented together. Whilst it is good that the majority of the patients who had undergone surgery knew that trichiasis and trachoma can lead to blindness, it is of concern that only two fifths knew that the two are linked. Finding ways to improve health education in communities where trachoma is endemic to increase understanding of the disease may encourage patients to participate in all aspects of the SAFE strategy rather than just seeking help when they have already developed trichiasis and potentially sight-threatening disease.

Action also needs to be taken to ensure the quality and sustainability of the surgical service for trichiasis. Habtamu et al have already identified the fact that surgeons need better support and supervision and that the management of supply chain needs to be addressed to ensure that the appropriate surgical instruments and materials are available (35). In

addition, methods need to be explored by which patients can be followed up and surgical outcomes audited. This is important both for ensuring the best ultimate outcome for the patient and for providing feedback on the performance of the surgeons. Following up patients in this setting is undoubtedly a complex and costly undertaking but research into the optimum time and place for follow up and the potential cost versus benefit is warranted.

It is a generally accepted fact that surgeons who perform a particular operation frequently have better results than those who perform the same operation infrequently but more research into how many trichiasis operations each IECW should be performing each year to maintain their competencies would be informative. Most importantly, longitudinal studies are required to examine the effects of trichiasis recurrence and surgical complications on the development of corneal opacity post-operatively to help determine whether this association is causative.

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