# Efficacy and safety of oncoplastic surgery plus drug therapy for chronic tuberculous granulomatous mastitis

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#### \_ S U M M A R Y

BACKGROUND: Chronic tuberculous granulomatous mastitis (CTGM) is a rare form of tuberculosis (TB) treated primarily with anti-TB drugs. Oncoplastic surgery (OS) has been proposed as adjuvant therapy for CTGM. METHOD: We followed for 1 year every CTGM patients and assessed the efficacy (defined as non-recurrence and no need for corticosteroids) and safety attributable to the standard anti-TB drugs therapy with and without OS.

RESULTS: We analysed 128 CTGM cases, including 78 (61%) treated with OS plus anti-TB drugs and 50 (39%) with anti-TB drugs only. We observed a significantly higher efficacy among those exposed vs. unexposed to OS (100% vs. 92%; prevalence ratio [PR] 1.09, 95% CI

CHRONIC TUBERCULOUS granulomatous mastitis (CTGM) is a rare extrapulmonary form of tuberculosis (TB), first described in 1829,<sup>1</sup> that predominantly affects premenopausal women, who are breastfeeding or using oral contraceptives.<sup>2</sup> In countries that are endemic to TB, such as Bangladesh and Peru, CTGM can represent 3–6% of all cases of extrapulmonary TB,<sup>3,4</sup> 1% of the TB cases reported in the country<sup>4</sup> and 0.3% of all mammary pathologies.<sup>5</sup> Despite being a rare disease, CTGM represents a differential diagnosis for every female patient with granulomatous mastitis, particularly in developing countries endemic to TB.<sup>6</sup>

Diagnosing and treating CTGM cases represents a challenge for physicians because diagnostic tests, as well as available treatments, have limited certainty and efficacy.<sup>7,8</sup> CTGM is often confused with pyogenic mammary, carcinomas or abscesses.<sup>9</sup> It is therefore recommended to use fine-needle aspiration cytology or histopathological examinations to provide a definitive diagnosis.<sup>10,11</sup> Regardless of the diagnostic method used, the identification of the tuberculous bacilli in breast tissue is difficult because of the paucibacillary nature of the disease.<sup>12</sup> Patients often respond to the standard 9 months' anti-TB drug treatment, and surgical excision can be reserved for

1.00–1.18), with no difference in the number of complications (21% vs. 8%; PR 2.56, 95% CI 0.91–7.26). We also observed that the incidence of post-operative complications decreased by 50% when OS was postponed from after Month 1 to after completing Month 2 of anti-TB drugs treatment (19% to 8%; PR 0.46, 95% CI 0.13–1.62).

CONCLUSION: OS appears to represent an efficacious and safe adjuvant therapy when combined with anti-TB drugs in the treatment of CTGM patients, but clinical trials are needed to prove this observation.

**KEY WORDS**: tuberculosis; breast tuberculosis; treatment; oncoplastic surgery; granulomatous mastitis

refractory cases.<sup>13</sup> The combination of pharmacological and surgical therapies has been reported as efficacious; however, it often requires further reconstructive surgery due to anti-aesthetic results.<sup>14</sup> Previous estimates reported that the proportion of CTGM cases requiring surgical treatment as adjuvant therapy to anti-TB drug treatment ranges from 32% to 70%.<sup>15,16</sup>

Oncoplastic surgery (OS) is the combination of oncological surgery with plastic surgery techniques that arose from the demand for better cosmetic results in women who have breast cancer.<sup>17</sup> This approach prevents amputation of the mammary gland and has been widely described in the literature as an alternative to treatment of a variety of breast benign pathologies and tumours, including large phyllodes tumours, with positive outcomes.<sup>18,19</sup>

The present study aimed to assess the efficacy and complications rates attributable to OS as adjuvant treatment to anti-TB drugs in patients with CTGM.

# **METHODS**

## Study design

We performed a cohort study on patients diagnosed with CTGM who completed the standard 9 months'

Correspondence to: Antonio M Quispe, School of Medicine, Universidad Continental, Jr Junin 355, Miraflores, Lima 15046, Peru. email: aquispeg@continental.edu.pe; drantonioquispe@gmail.com Article submitted 19 July 2019. Final version accepted 30 October 2019. anti-TB drug treatment with (exposed) and without (unexposed) OS at the Grau Emergency Hospital (GEH), EsSalud, Lima, Peru. We compared both cohorts in terms of efficacy (no recurrent disease and no need of corticosteroids) and safety (no complications). To this end, we revised their clinical charts, laboratory and pathology records from each cohort member.

#### Population and sample

The inclusion criteria were 1) patients diagnosed with CTGM, confirmed by histopathology or molecular biology; 2) have completed the standard 9 months' anti-TB drug treatment for extrapulmonary TB (isoniazid, rifampicin, pyrazinamide and ethambutol for 2 months; isoniazid and rifampicin for 7 months). Exclusion criteria included 1) multidrug-resistant TB (MDR-TB); 2) subjects requiring non-standard anti-TB drugs for any reason. To maximise the power of the study, we recruited every eligible subject.

# Oncoplastic surgery

When used as adjuvant therapy for CTGM, OS aims to 1) achieve a complete resection of the TB granuloma; 2) immediately reconstruct the affected breast; and, 3) minimise wound scars. During surgery planning, the breast is divided schematically into seven segments (Supplementary Figure S1). Surgeons use this segmentation to decide which oncoplastic technique to use, given that some segments have less breast tissue (segments VI-VII) than others.<sup>20</sup> Eligibility criteria for candidates to OS includes: 1) CTGM patients after completing the Month 1 (2010-2015 period) or Month 2 (2016-2018 period) of anti-TB drugs treatment; 2) CTGM affecting <20% of the breast volume (up to  $\sim$ 8 cm of injury in large breasts and up to  $\sim 2$  cm in small breasts); 3) subjects with available flap donor sites that match the lesion size. OS contraindications include 1) little breast without ptosis; 2) skin resections outside the mammoplasty area; 3) tobacco addiction or uncontrolled diabetes; or, 4) injuries that involve over 50% of the breast.<sup>21</sup> Possible complications are similar to partial mastectomies,22,23 and includes haematoma/bleeding, wound infection, pain, formation of hard scar tissue, seroma, deformity of the breast, upper limb lymphoedema, dehiscence of the incision, glandular/fat necrosis, and marginal necrosis of the skin and/or areola-nipple complex.

# Data collection and statistical analysis

We collected the study data by accessing the hospital admission database and identifying every eligible subject diagnosed with CTGM during the period 2005–2018. We then reviewed each of their medical records, including their laboratory and pathology records. For data quality control, we used doubledata entry method, value limits, pre-coded categories

and character limits. After quality control, we performed a descriptive analysis summarising numerical variables with their mean and standard deviations: and categorical variables with their absolute and relative frequencies. We then compared OS exposed vs. unexposed using patient demographics and clinical characteristics. We estimated and compared treatment efficacy by combining the incidence of recurrences and the use of corticosteroids, and assessed treatment safety as no overall drugs side effects or post-operative complications. We also performed a secondary analysis comparing subjects treated with OS during periods 2010-2015 and 2016–2018 to assess whether postponing the surgery from after completing Month 1 to after completing Month 2 of anti-TB drug treatment had any impact on study outcomes. We used Student's t-test for to compare means, Fisher's exact test to compare proportions, and robust Poisson regression models to estimate prevalence rates (PRs) for efficacy and safety outcomes, both unadjusted and adjusted for potential confounders. In all cases, we used a confidence interval (CI) of 95% and performed data analysis using the STATA<sup>™</sup> MP v14.0 statistical package (Stata Corp LP, College Station, TX, USA).

# Ethical aspects

The GEH health network Institutional Scientific Committee and the Institutional Review Committee reviewed and approved the study protocol. In all cases, patients were required to consent before the intervention, and participants data were coded to protect their identity. Study forms and codes were protected and handled only by the study researchers.

# RESULTS

# Study population

During the period 2005–2018, the GEH reported a total of 130 cases of CTGM. Of these, two subjects were excluded from our analysis, including one from each cohort. One case was infected with MDR-TB, and the other case requiring treatment for isoniazid-resistant TB. We therefore analysed a total of 128 CTGM cases, including 78 (61%) patients treated with anti-TB drug treatment plus OS and 50 (39%) treated with anti-TB drugs treatment only (Table 1). The mean age was  $35 \pm 9$  years (range 19–80) and the mean disease duration was  $3.9 \pm 2.2$  months (range 1–10). The mean follow-up time was  $16.7 \pm 10.6$  months (range 1–84). Most patients were women (99%), from Lima (79%), with no personal (91%) or family (91%) history of TB.

#### Diagnosis of tuberculosis

Most exposed subjects had a lesion with a size of 5-8 cm (44%), and most unexposed subjects had a lesion > 8 cm (54%). In most cases, CTGM affected the

Variable	Total n (%)	Drugs only n (%)	Drugs + OS n (%)
Total	128 (100)	50 (39)	78 (61)
Period 2005–2009 2010–2015 2016–2018 Disease duration, months, mean ± SD Follow-up, months, mean ± SD Age, years, mean ± SD Male sex Unemployed From Lima, Peru Chronic comorbidities Family history of TB Bilateral	$\begin{array}{c} 11 \ (8.6) \\ 70 \ (54.7) \\ 47 \ (36.7) \\ 16.3 \pm 0.9 \\ 3.9 \pm 2.2 \\ 35.3 \pm 8.9 \\ 1 \ (0.8) \\ 37 \ (28.9) \\ 98 \ (76.6) \\ 11 \ (8.6) \\ 16 \ (12.5) \end{array}$	$\begin{array}{c} 11 \ (22.0) \\ 27 \ (54.0) \\ 12 \ (24.0) \\ 12.4 \ \pm \ 5.2 \\ 4.0 \ \pm \ 2.3 \\ 36.3 \ \pm \ 10.1 \\ 1 \ (2.0) \\ 16 \ (32.0) \\ 43 \ (86.0) \\ 5 \ (10.0) \\ 6 \ (12.0) \end{array}$	$\begin{array}{c} 0 \ (0.0) \\ 43 \ (55.1) \\ 35 \ (44.9) \\ 18.7 \pm 11.8 \\ 3.8 \pm 2.2 \\ 34.6 \pm 8.1 \\ 0 \ (0.0) \\ 21 \ (26.9) \\ 50 \ (70.5) \\ 6 \ (7.9) \\ 10 \ (12.8) \end{array}$
Quadrants Upper outer Upper inner Lower outer Lower inner Positive mammography Positive chest X-ray Positive TST Positive sputum smear Positive sputum culture	3 (2.3) 98 (76.6) 18 (14.1) 11 (8.6) 1 (0.8) 37 (28.9) 4 (3.1) 11 (8.6) 3 (2.3) 8 (6.3)	$\begin{array}{c} 1 (2.0) \\ 43 (86.0) \\ 2 (4.0) \\ 5 (10.0) \\ 0 (0.0) \\ 15 (30.0) \\ 2 (4.0) \\ 5 (10.0) \\ 2 (4.1) \\ 4 (8.0) \end{array}$	2 (2.6) 55 (70.5) 16 (20.5) 6 (7.7) 1 (1.3) 22 (28.2) 2 (2.6) 6 (7.7) 1 (1.3) 4 (5.1)
Size of lesion, cm $\leq 5$ >5-8 >8	48 (37.5) 50 (39.1) 30 (23.4)	8 (16.0) 15 (30.0) 27 (54.0)	40 (37.5) 35 (44.9) 3 (3.9)

Table 1	Characteristics	of cohort members (	(n = 128) by ex	(posure to OS
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OS = oncoplastic surgery; SD = standard deviation; TB = tuberculosis; TST = tuberculin skin test.

right breast (72%) and upper outer quadrant (77%). Few patients had positive mammography (29%) or chest X-ray (3%), and all of these tested positive on ultrasound. Most patients (91%) tested negative to the tuberculin test, and only 9% of the patients had indeterminate results on purified protein derivative (PPD). Similarly, few patients tested positive using sputum smear microscopy (2%) or sputum culture (5%). Every CTGM case was confirmed for either using histopathology (Supplementary Data Figures 1A–B) or molecular biology, including one using Xpert<sup>®</sup> MTB/RIF (Cepheid, Sunnyvale, CA, USA) (1 positive/1 tested) or six using polymerase chain reaction (6 positive/9 tested).

#### Oncoplastic surgery

Since its inception in 2010, a total of 67 patients has received OS. Most patients were operated using 'lateral' mammoplasty techniques (48%) (Supplementary Figure S2A–C), followed by the 'horizontal' (27%) (Supplementary Figure S3A–C), the 'round block' (15%) (Supplementary Figure S4A–B) and the 'vertical' (10%) (Supplementary Figure S5A–C) mammoplasty techniques due the location of lesion.

#### Treatment efficacy

Both cohorts exhibited high efficacy, but those exposed to OS showed significantly higher efficacy than those unexposed to OS (100% vs. 92%; PR 1.09, 95% CI 1.00–1.18; P = 0.046). None of the

patients exposed to OS required corticosteroids, and none of them recurred over time. However, among those treated with anti-TB drugs only, three patients required corticosteroids (0% vs. 6%, P = 0.0286) and one recurred 3 months after having completed the 9 months' of anti-TB drug treatment (0% vs. 2%, P =0.2130). Qualitatively, the patients treated with OS plus anti-TB drugs exhibited more aesthetic results (Supplementary Figures S2B, S2C, S3C, S4B and S5C) than those treated with anti-TB drugs only (Supplementary Figures S6A and S6B). At the bivariate regression analysis, we found that the potential associated factors to treatment success included OS, positive mammography, precedence from Lima; lesions located in the upper outer quadrant, chronic comorbidities, a positive PPD, a positive chest X-ray, and bacteriological sputum positivity. However, in the multivariate regression analysis we found that the main associated factors to treatment success were OS (adjusted PR [aPR 1.09, 95% CI 1.00-1.18; P = 0.044) and a positive mammography (aPR 1.05, 95%) CI 1.00–1.10; P = 0.048).

#### Treatment safety

Overall, we did not find a statistically significant difference when comparing the exposed and unexposed to OS in terms of overall complications rates (21% vs. 8%; PR = 2.56, 95% CI 0.91–7.26; P = 0.076) and drug sides effects (8% vs. 8%; PR = 0.96, 95% CI 0.28–3.25; P = 0.950) (Table 2). However,

Outcomes	Drugs + OS			Drugs alone			Effect	
	п	%	95% CI	п	%	95% CI	PR	95% CI
Efficacy	78	100	100–100	46	92	84 to 100	1.09	1.00–1.18
Failure	0	0	0	4	8	0 to 16	$2.4^{-08}$	9.1 <sup>-09</sup> -6.8 <sup>-09</sup>
Recurrence	0	0	0	1	2	-2 to 6	$2.4^{-08}$	3.4 <sup>-09</sup> -1.7 <sup>-07</sup>
Corticosteroid use	0	0	0	3	6	1 to 12	$2.4^{-08}$	7.8 <sup>-09</sup> -7.4 <sup>-08</sup>
Safety	16	21	11 to 30	4	8	0 to 15	2.56	0.91-7.26
Drug side effects	6	8	2 to 14	4	8	0 to 16	0.96	0.28-3.25
Post-operative complications	11	14	6 to 22	_	—	_	—	—

 Table 2
 Efficacy and safety of using anti-tuberculosis drugs with and without OS to treat patients with chronic tuberculous granulomatous mastitis

OS = oncoplastic surgery; CI = confidence interval; PR = prevalence ratio.

we estimated an incidence of post-operative complication of 14% (95% CI 6–22), including wound dehiscence (incidence 8%, 95% CI 2–14), slight necrosis of the wound edge (incidence 4%, 95% CI –1 to 8) and wound infections (incidence 3%, 95% CI –1 to 6). However, these complications decreased by 50% since surgeons start postponing the surgery from after completing Month 1 (2010–2015 period, 43/78) to after completing the Month 2 (2016–2018 period, 35/78) of anti-TB drugs treatment (19% to 8%; PR=0.46, 95% CI 0.13–1.62; P=0.227) (Table 3).

# Regression analysis

Overall, we found that possible factors associated with treatment success included OS, positive mammography, being a resident of Lima, lesions in the upper outer quadrant, chronic comorbidities, a positive PPD, a positive chest X-ray and bacteriological sputum positivity. However, in the multivariate regression analysis, we found that the main associated factors to treatment success were OS and a positive mammography (Table 4).

## DISCUSSION

Our findings support the hypothesis that OS represents an efficacious adjuvant therapy when used in combination with anti-TB drugs to treat CTGM patients, exhibiting a similar efficacy as using anti-TB drugs treatment alone. Also, we observed that OS was associated with a low rate of post-operative complications, which surgeons were able to halt by postponing the surgery from after completing Month 1 to after completing Month 2 of anti-TB drug treatment. In our study, we observed a treatment efficacy as high as the one previously reported by two studies that assessed standard surgery techniques (breast mastectomy) plus anti-TB drugs treatment, meaning a 100% efficacy with 0% recurrence. However, both studies were carried out had limited sample sizes, reporting outcomes with only 16 patients<sup>24</sup> and 11 patients,<sup>25</sup> respectively.

We observed in our study that less than the fifth part of the total cases treated with OS presented postoperative complications, with wound dehiscence as the most frequent. A previous experience with breast cancer patients treated with OS reported slightly fewer complications than those treated with conventional breast-conserving surgery (5.5% vs. 6.6%), including seromas (1.7% vs. 2.6%), infection (2.3% vs. 2.0%) and skin necrosis (0.9% vs. 0.6%).<sup>26</sup> Nevertheless, OS is considered a safe surgical technique in breast cancer patients.<sup>27</sup>

To reduce the incidence of post-operative complications, we postponed the surgery from after completing Month 1 (2010–2015 period) to after completing Month 2 (2016–2018 period) of anti-TB drug treatment. By doing so, we estimated that we could reduce the incidence and the risk of postoperative complications to half; however, we failed to prove that such a difference was statistically significant. Nevertheless, we believe that by allowing more time to patients' body to respond to the anti-TB drug treatment, we reduced the chances of postoperative complications, particularly wound dehiscence and the necrosis of wound edges.

CTGM is a rare disease that represents less than

**Table 3**Post-operative complications among those chronic tuberculous granulomatous mastitis cases treated with oncoplasticsurgery before (2010–2015) and after (2016–2018) postponing surgery from after completing Month 1 to after completing Month 2of anti-TB drugs treatment

Post-operative complications	2010–2015			2016–2018			Effect	
	n	%	95% CI	n	%	95% CI	PR	95% CI
Total	8	19	6 to 30	3	8	-1 to 18	0.46	0.13–1.62
Wound dehiscence	4	9	0 to 18	2	6	-2 to 14	0.61	0.12–3.19
Slight necrosis of the wound edges	2	5	-1 to 11	1	3	-3 to 9	0.61	0.06-6.60
Wound infection	2	5	-1 to 11	0	0	_	$6.4^{-08}$	1.6 <sup>-08</sup> -2.6 <sup>-07</sup>

CI = confidence interval; PR = prevalence ratio.

Factor	PR (95% CI)	P value	aPR (95% CI)	P value
Oncoplastic surgery	1.09 (1.00–1.18)	0.046	1.09 (1.00–1.18)	0.044
Positive mammography	1.05 (1.00-1.09)	0.046	1.05 (1.00-1.10)	0.048
From Lima, Peru	0.96 (0.92-1.00)	0.046		
Site of disease: upper outer quadrant	0.96 (0.92-1.00)	0.046		
Chronic comorbidities	1.04 (1.00-1.07)	0.046		
Positive TST	1.04 (1.00-1.07)	0.046		
Positive chest X-ray	1.04 (1.00-1.07)	0.046		
Sputum positive for <i>M. tuberculosis</i>	1.04 (1.00-1.07)	0.046		
Site of disease: bilateral	0.68 (0.31–1.53)	0.353		
Size of the lesion, cm				
<5	Reference			
>5-8	0.98 (0.94–1.02)	0.319		
>8	0.90 (0.80–1.02)	0.085		
Duration of illness, months	0.99 (0.98–1.01)	0.378		
Age	1.00 (0.99–1.01)	0.059		
Family history of TB	0.96 (0.86-1.10)	0.575		
Unemployed	0.99 (0.97–1.02)	0.546		
Follow-up time, months	1.00 (0.99–1.00)	0.794		

Table 4 Factors associated with treatment success

PR = prevalence ratio; CI = confidence interval; aPR = adjusted PR; TST = tuberculin skin test; TB = tuberculosis.

1% of cases in Peru. In our study, women with CTGM had an average age of 35 years, with an age range of 19-67 years. A previous study carried out in Lima reported an average age in women with CTGM of 33 years, with an age range between 11 and 51 years.<sup>15</sup> These values are consistent with the mean age of people with TB (35 years), whose age range is within that of women of childbearing age.<sup>4</sup> CTGM in men is more unusual than in women,<sup>28</sup> but have not been reported yet in Peru. In our study, we reported one case of CTGM in an 80 year-old man, with 1 month of evolution that affected the lower outer quadrant of his right breast and responded successfully to the anti-TB drug treatment alone. This subject tested positive in the bacteriological culture of his biopsy, which, together with fine-needle aspiration, represent the most common diagnostic method used in men.<sup>29</sup> Overall, CTGM men patients respond to anti-TB drug treatment and have a good prognosis, and rarely requiring adjuvant surgical therapy.<sup>28</sup>

Regarding disease presentation, we observed that in our experience, CTGM mainly affected the right breast, and that it was more common in the upper quadrants. Other studies have reported that CTGM predominantly affects the left breast and the upper quadrants,<sup>30</sup> but with a significant fraction (~26%) involving multiple quadrants.<sup>31</sup> Some studies have reported that CTGM affects the right and left breast indistinctively, with rare cases affecting both breasts at the same time.<sup>16,29</sup> Overall, from the medical perspective, it is fair to assume that CTGM is unilateral without specific side predominance, but more importantly, it predominantly affects the upper quadrants which are more susceptible to an efficacious surgical treatment.

To our knowledge, this is the most extensive series of CTGM cases treated with OS plus anti-TB drug treatment reported in the literature. However, one of

the main limitations of our study was contradictorily the limited sample size and study power. We attempted to solve this limitation by assessing the full cohort, expanding the study period and by maximising data quality controls. Another significant limitation is that our recurrence rate may have been biased due to the use hospital records, which are not ideal for follow-up study subjects. However, our TB programme has an excellent record in tracing patients due to their experience in treating TB patients with full coverage insurance. A third important study limitation is that we did not explore whether patients were satisfied with the treatment outcomes or its potential impact on the mental health of the patients, which were both presumed to have been favourable to OS.

In conclusion, OS plus pharmacological treatment might represent an efficacious and safe adjuvant therapy to the anti-TB drug treatment in patients with CTGM. However, there is a need for randomised controlled clinical trials to prove this observation. It is recommended to use a larger sample size in future studies, as well as the measurement of outcomes such as patients' satisfaction, quality of life and mental health to broadly assess the real impact of OS in the treatment of CTGM patients.

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Conflicts of interest: none declared.

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#### \_\_ R É S U M É

CONTEXTE : La mastite granulomateuse tuberculeuse chronique (CTGM) est une forme rare de tuberculose (TB) traitée en premier lieu par des médicaments anti-TB. La chirurgie oncoplastique (OS) a été proposée comme traitement adjuvant de la CTGM.

MÉTHODE : Nous avons suivi pendant un an chaque patient CTGM et évalué l'efficacité (définie comme une absence de récurrence et de besoin de corticostéroïdes) et la sécurité attribuable au traitement standard anti-TB avec et sans OS.

RÉSULTATS : Nous avons analysé 128 cas de CTGM, incluant 78 cas (61%) traités par OS plus médicaments anti-TB et 50 cas (39%) sous médicaments anti-TB seuls. Nous avons observé une efficacité significativement plus élevée parmi les patients exposés ou pas à l'OS (100% contre 92% ; ratio de prévalence [PR] 1,09 ; IC 95% 1,00–1,18), sans différence en termes de complications (21% contre 8% ; PR 2,56 ; IC 95% 0,91–7,26). Nous avons également observé que l'incidence des complications post opératoires avait diminué de 50% quand l'OS a été différée de la fin du premier mois de traitement à l'achèvement du deuxième mois de traitement anti-TB (19% à 8% ; PR 0,46 ; IC 95% 0,13–1,62).

CONCLUSION : L'OS semble représenter un traitement adjuvant efficace et sûr en combinaison avec les médicaments anti-TB dans le traitement des patients CTGM, mais des essais cliniques sont nécessaires pour confirmer cette observation.

#### \_ R E S U M E N

MARCO DE REFERENCIA: La mastitis crónica granulomatosa tuberculosa (CTGM) es una forma rara de tuberculosis (TB) tratada principalmente con medicamentos antituberculosos. La cirugía oncoplástica (OS) ha sido propuesta como una terapia adyuvante para CTGM.

MÉTODOS: Durante un año seguimos a todos los pacientes con CTGM y evaluamos la eficacia (definida como sin recurrencia y sin necesidad de corticosteroides) y seguridad atribuible a la terapia estándar de medicamentos antituberculosos con y sin OS.

RESULTADOS: Analizamos 128 casos de CTGM, incluidos 78 (61%) tratados con OS más medicamentos antituberculosos y 50 (39%) solo con medicamentos antituberculosos. Se observó una eficacia significativamente mayor entre los expuestos a OS versus los no expuestos a OS (100% frente a 92%; relación de prevalencia [RP] 1,09; IC 95% 1,00–1,18), sin diferencias en las complicaciones en general (21% vs. 8%; RP 2,56; IC 95% 0,91–7,26). Además, observamos que la incidencia de complicaciones postoperatorias disminuyó en un 50% cuando se pospuso la OS de después de completar el primer mes hasta después de completar el segundo mes de terapia con medicamentos antituberculosos (19% a 8%; RP 0,46; IC 95% 0,13– 1,62).

CONCLUSIÓN: La OS parece representar una terapia adyuvante eficaz y segura cuando se combina con medicamentos antituberculosos en el tratamiento de pacientes con CTGM, pero se necesitan ensayos clínicos para probar esta observación.