A staged treatment programme for combined gastroduodenal and biliary pathology in military personnel: 12-month comparative outcomes

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Abstract

Objective. To compare a staged treatment programme with standard care in military personnel with combined gastroduodenal and biliary pathology.

Materials and methods. The treatment cohort included 64 patients, 31 receiving standard care and 33 a staged programme. The source describes stratified allocation using opaque envelopes. The programme combined regular meals, hydration and treatment directed at mucosal injury, reflux and biliary dysfunction. Symptoms, gallbladder contractility and 12-month clinical outcomes were examined from aggregate tables.

Results. At 12 weeks, GSRS total scores were 2.37 ± 0.07 with standard care and 1.81 ± 0.06 with staged care ($p < 0.001$; mean ± SEM). Gallbladder contractility was 44.7 ± 2.5% versus 53.7 ± 2.1% ($p = 0.008$). Twelve-month exacerbations occurred in 18/31 patients (58.1%) and 7/33 (21.2%; $p = 0.004$), respectively. Median duty days lost were 9 [3–18] and 2 [0–5]. Comparative differences in erosion healing and H. pylori eradication were not statistically significant.

Conclusion. Staged care was associated with improved symptoms, contractility and fewer recorded exacerbations. The small, open-label, bundled comparison does not identify the effect of an individual drug or establish reversal of atrophy or metaplasia.

Keywords: gastroduodenal disease; biliary dysfunction; military personnel; duodenogastric reflux; GSRS; staged treatment

Introduction

Gastroduodenal symptoms and biliary dysfunction may coexist, but their coexistence does not establish a single cause for every complaint. Reflux, mucosal injury, gallbladder motility and symptom perception require separate assessment. A treatment programme that addresses several of these domains should therefore report each endpoint with its own definition.

Clinical research has examined bile reflux gastropathy in patients with dyspeptic symptoms [1]. Ursodeoxycholic acid has also been evaluated after distal gastrectomy, where the altered anatomy differs substantially from that of a patient with an intact stomach [2]. Itopride trials concern functional dyspepsia and cannot by themselves validate a combined gastroduodenal–biliary treatment algorithm [3].

The present study compared a staged programme with standard care among military personnel with combined pathology. The principal questions were whether symptom scores and functional measurements differed at 12 weeks and whether recorded exacerbations differed over 12 months. Microbiological, endoscopic and service-related outcomes were retained as distinct secondary comparisons.

Materials and methods

Population and design

The wider investigation was conducted during 2022–2025. This manuscript focuses on 64 patients aged 18–50 years with combined gastroduodenal and biliary pathology and symptoms lasting at least three months. Thirty-one received standard care and 33 the staged programme. The source describes stratification by mucosal findings, H. pylori status and gallbladder hypokinesia, with allocation using opaque envelopes.

The cohort was examined with endoscopy and ultrasound. Exclusions included gallstones, previous relevant surgery, malignancy, cirrhosis, viral hepatitis, pancreatic insufficiency, active bleeding or stenosis, and uncontrolled diabetes. The intervention cohort is not combined with the other disease or healthy-reference groups in the wider dissertation.

Treatment programme

Standard care included omeprazole 20 mg twice daily for four weeks, symptomatic medication and dietary advice. H. pylori-positive patients received 14 days of amoxicillin 1 g, clarithromycin 500 mg and omeprazole 20 mg, each twice daily. The staged programme added regular meals, hydration and treatment selected according to the documented clinical pattern.

During the initial phase, the source protocol used ursodeoxycholic acid at 10 mg/kg at night for reduced gallbladder contractility, itopride 50 mg three times daily for duodenogastric reflux, and rebamipide 100 mg three times daily for eight weeks. An alginate–antacid preparation was added for elevated aspirate bile-acid concentration. Subsequent treatment during weeks 5–12 was adjusted to residual motility, reflux and mucosal findings. Maintenance courses during months 4–12 were linked to relapse and anticipated field exposure.

These details describe study exposures, not an independently validated treatment recommendation. Several medications and organisational measures changed together. Antibiotic selection in another setting requires contemporary susceptibility-based assessment rather than automatic reproduction of the historical regimen [4].

Outcomes and statistical analysis

The principal reported assessments were GSRS at 12 weeks, ultrasound-derived gallbladder contractility, endoscopic reflux grade, aspirate bile acids and clinical exacerbation during 12 months. H. pylori eradication, erosion healing and sludge resolution used only participants with the corresponding baseline finding as their denominators.

Means are presented with standard errors. Duty days lost and bile-acid measurements are reported as median [interquartile range]. Tests and confidence intervals were reproduced from the aggregate source tables. No patient-level reconstruction or new multivariable analysis was performed. The source describes blinded ultrasound and pathological assessment, but open-label treatment and exclusion of missed 12-week visits limit an intention-to-treat interpretation.

Results

Baseline treatment-group characteristics

Table 1. Baseline profile of the combined-pathology treatment cohort

Characteristic	Standard (n = 31)	Staged (n = 33)
Age, years	32.7 ± 1.6	35.0 ± 1.5
Male sex, n	29	30
H. pylori positive, n	18	21
Mucosal erosions, n	14	17
Biliary sludge, n	12	11
Gallbladder contractility, %	42.5 ± 2.4	41.4 ± 2.3
GSRS total	3.43 ± 0.15	3.50 ± 0.11
Reactive gastropathy index	4.94 ± 0.39	5.21 ± 0.33

Continuous values are mean ± SEM. Infection, erosions and sludge overlap; their counts must not be added to form a total.

The reported baseline GSRS and gallbladder-contractility means were close between groups. H. pylori infection affected 18 standard-care and 21 staged-care patients. Erosions were recorded in 14 and 17, while sludge was present in 12 and 11, respectively. These differences define the outcome-specific denominators used later.

The combination of gastroduodenal and biliary findings was heterogeneous. Not every participant had every recorded abnormality. As a result, the response of an infected or erosive subgroup cannot be presented as the response of all 64 patients.

The locally derived treatment thresholds were used within the source protocol. They are not presented here as externally validated cut-offs for assigning therapy in other populations.

Gallbladder contractility over follow-up

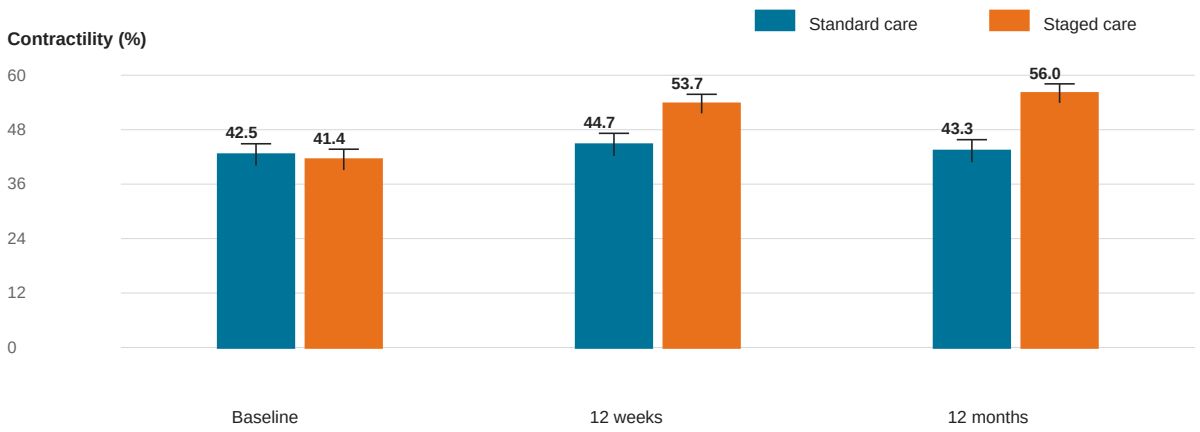


Figure 1. Reported gallbladder contractility at the three assessments.

Error bars represent SEM. Between-group p values were 0.739 at baseline, 0.008 at 12 weeks and <0.001 at 12 months.

The staged-care group had a higher mean contractility at 12 weeks and 12 months. The standard-care group showed a smaller change from baseline. These are group summaries from the scheduled examinations, not continuous measurements of motility.

The persistence of a between-group difference at 12 months concerns the complete staged programme, including maintenance measures. It cannot distinguish an effect of ursodeoxycholic acid from changes in meals, symptom management or other medication. Ultrasound acquisition conditions and individual adherence would be needed for a more detailed interpretation.

Symptomatic, endoscopic and subgroup outcomes

Table 2. Selected short-term outcomes with explicit denominators

Outcome	Standard	Staged	p
12-week GSRS total	2.37 ± 0.07	1.81 ± 0.06	<0.001
Reflux grade II–III, n/N	16/31	6/33	0.008
Erosion healing, n/N	10/14	16/17	0.148
H. pylori eradication, n/N	14/18	19/21	0.387
Sludge resolution, n/N	4/12	9/11	0.036

GSRS is mean ± SEM. Healing, eradication and sludge outcomes concern distinct baseline-positive subsets; their denominators are not interchangeable.

Lower total GSRS scores and fewer grade II–III reflux findings were recorded with staged care. Sludge resolution was also more frequent in its small baseline-positive subgroup. In contrast, the erosion-healing and eradication comparisons did not reach the stated significance threshold.

Aspirate bile-acid concentration at 12 weeks was 0.54 [0.37–0.84] mmol/L under standard care and 0.25 [0.19–0.42] mmol/L under staged care ($p < 0.001$). This is a local measurement associated with the reflux assessment; it should not be interpreted as a systemic bile-acid exposure estimate.

At 12 months, the reactive gastropathy index was 4.08 ± 0.22 versus 2.27 ± 0.15 ($p < 0.001$). The source's atrophy and metaplasia endpoints had baseline differences and do not establish reversal of those lesions. They were not used as evidence for a disease-modifying histological effect.

Gastrointestinal symptom domains

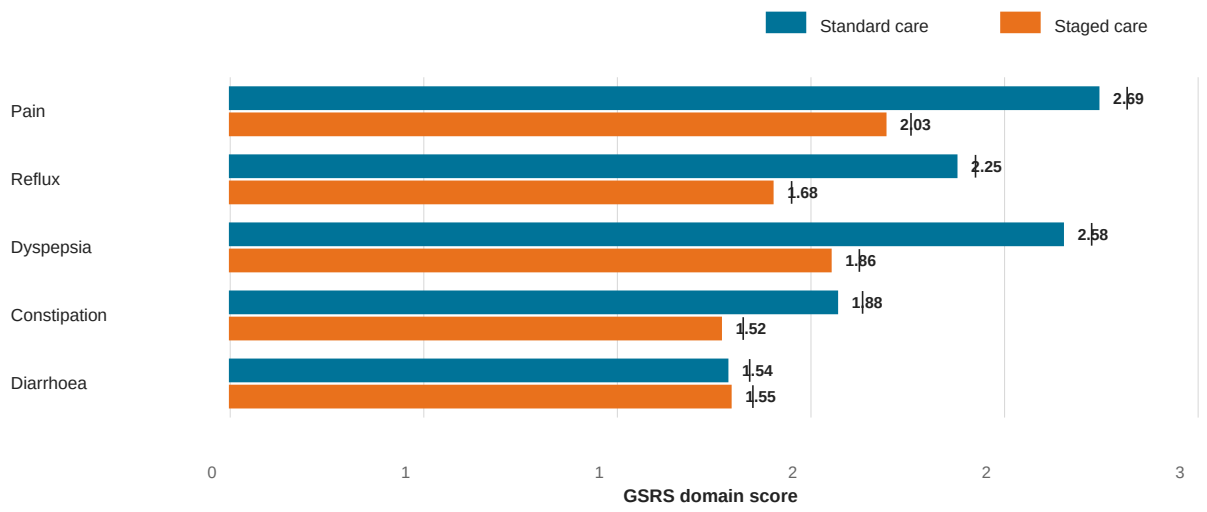


Figure 2. GSRS domain scores after 12 weeks.

Error bars represent SEM. Between-group p values were <0.001 for pain, reflux and dyspepsia, 0.002 for constipation and 0.902 for diarrhoea.

The largest residual symptom scores under standard care concerned pain and dyspepsia. Staged care was associated with lower values in these domains and in reflux and constipation. Diarrhoea scores were almost identical, and the comparison was not significant.

This pattern is more informative than a general assertion that every symptom improved more under staged treatment. The programme was directed at a heterogeneous combination of motility and mucosal findings, and its apparent benefit was not uniform across all GSRS domains. A domain-specific interpretation remains necessary even when the total score differs.

Twelve-month clinical outcomes

Table 3. Recorded exacerbation and service-related outcomes

Outcome	Standard (n = 31)	Staged (n = 33)
Exacerbation, n (%)	18 (58.1)	7 (21.2)
Repeated exacerbations, n	11	0
Hospitalisation, n	7	2
Duty days lost, median [IQR]	9 [3–18]	2 [0–5]
Any adverse event, n	7	8

Exacerbation: p = 0.004; repeated exacerbation: p < 0.001; hospitalisation: p = 0.078; duty days lost: p < 0.001. Adverse-event rates were similar (p = 1.000).

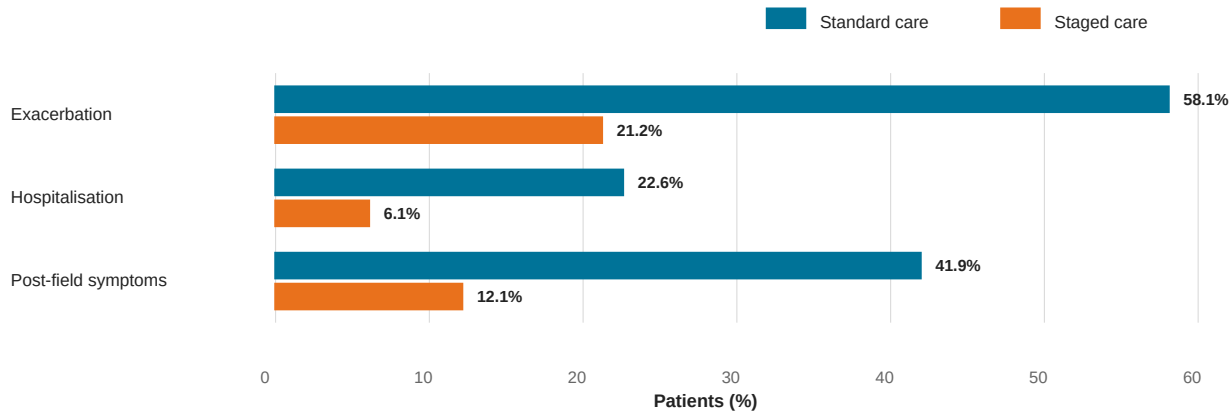


Figure 3. Selected clinical events during 12-month follow-up.

Events overlap. Exacerbation refers to the source clinical endpoint and is not synonymous with recurrent endoscopically confirmed peptic ulcer.

Discussion

Staged care was associated with lower symptom scores, improved reported contractility and fewer recorded exacerbations over 12 months. These outcomes describe different aspects of the clinical course and should not be collapsed into a single unspecified measure of “effectiveness”. The hospitalisation comparison, for example, was numerically favourable but not statistically significant.

Research on bile reflux gastropathy provides a clinical context for separating mucosal findings from dyspeptic symptoms [1]. The present study added a biliary-functional component, but the aggregate data do not establish that an improvement in contractility caused the reduction in symptoms or exacerbations.

The PEGASUS-D secondary analysis examined ursodeoxycholic acid after distal gastrectomy [2]. Its altered-anatomy population is not directly comparable with this cohort, and symptom outcomes did not simply mirror endoscopic bile-reflux findings. It is therefore insufficient to attribute the present programme’s symptom advantage to ursodeoxycholic acid alone.

Similarly, a placebo-controlled itopride trial addressed functional dyspepsia rather than the complete combined-pathology programme [3]. It supplies context for a prokinetic component, not validation of the source’s treatment thresholds. H. pylori eradication remains a separate therapeutic question, and the historical antibiotic regimen needs to be read in light of contemporary guidance [4].

Limitations

Only 64 patients contributed to the treatment comparison. The bundle changed several medications and behavioural measures simultaneously, while maintenance treatment varied according to response. Blinding was incomplete, and sequence generation, trial registration and the consequences of missed visits were not fully reported.

The available data were aggregated. They could not support independent checking of episode definitions, longitudinal adherence or the attribution of adverse effects. Multiple endpoints and small baseline-positive subgroups increase uncertainty. Differences in atrophy and metaplasia at follow-up cannot be interpreted as reversal because baseline imbalance and within-group change must also be considered. The findings concern the complete programme and require confirmation in a prospectively documented comparison.

Conclusion

In the reported 64-patient cohort, staged care was associated with more favourable symptom and contractility measurements and fewer 12-month exacerbations. Eradication, erosion healing and hospitalisation did not differ significantly between groups. The results support further study of an integrated approach but do not identify the efficacy of an individual drug or establish reversal of atrophy or metaplasia.

Declarations

Data provenance. The manuscript uses the treatment chapter of the supplied dissertation. All subgroup denominators were retained; no synthetic observations or new efficacy model was created. Historical treatment regimens are reported as study methods, not as current prescribing advice.

Ethics and consent. The ethics committee name, the approval number and the approval date, the consent documentation, the study registration and the participant-flow record require author confirmation before submission.

Author information, funding and competing interests. The co-author name was supplied for publication. The official English affiliation, corresponding e-mail, author contributions, funding sources and competing interests require confirmation.

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