

## Medium-term durability of giant hiatus hernia repair without mesh

RV Furtado<sup>1</sup>, SJ Vivian<sup>2</sup>, H van der Wall<sup>3</sup>, GL Falk<sup>1,2</sup>

<sup>1</sup>Concord Repatriation General Hospital, NSW, Australia

<sup>2</sup>Sydney Heartburn Clinic, Lindfield, NSW, Australia

<sup>3</sup>Concord Nuclear Imaging, NSW, Australia

### ABSTRACT

**INTRODUCTION** This is the second report on objective review of 100 patients who underwent composite fundoplication-cardioplexy for repair of giant hiatus hernia (GHH) at a median of 24 months following surgery. Outcomes were objective follow-up by endoscopy and quality of life (QoL) by Gastrointestinal Quality of Life Index (GIQLI), modified Visick scores and dysphagia scores. The initial report for this cohort suggested a low objective recurrence rate (9%) and substantial improvements in QoL indices.

**METHODS** The rate of hernia recurrence was assessed with Kaplan–Meier analysis and covariates were analysed with the Cox proportional hazards model. Paired t-tests and related samples Wilcoxon signed-rank tests were used to compare QoL scores. Unpaired data were compared with the independent samples t-test and Mann–Whitney U test.

**RESULTS** Objective review was obtained in 97% of the patients. There were five recurrences of hernias that had a vertical height of >2cm from the diaphragmatic hiatus, with three patients requiring reoperation for severe dysphagia. Small recurrences (<2cm) occurred in 20 patients. The median time to recurrence was 40 months (95% confidence interval: 34–46 months). At two years, recurrence of any size had occurred in 24% of cases. At follow-up review (median: 27 months), the mean GIQLI score was 109 ( $p=0.279$ ), the median modified Visick score was 2 ( $p=0.954$ ) and the median dysphagia score was 41 ( $p=0.623$ ). There was no evidence that the GIQLI score ( $p=0.089$ ), the modified Visick score ( $p=0.339$ ) or the dysphagia score ( $p=0.445$ ) changed significantly after recurrence.

**CONCLUSIONS** There was a sustained improvement in overall QoL and reflux scores after GHH repair. QoL scores showed persistent improvement in reflux and overall health, even in the subgroup with recurrence. The majority (80%) of recurrences were small and recurrent herniation did not appear to significantly change QoL. The rates of recurrence and QoL are comparable with those for other methods of repair.

### KEYWORDS

Paraoesophageal hiatus hernia – Laparoscopy – Follow-up study – Quality of life

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### CORRESPONDENCE TO

Ruelan Furtado, E: ruelanfurtado@yahoo.co.uk

Giant hiatus hernia (GHH) increasingly presents for surgical repair.<sup>1</sup> Management of the short oesophagus,<sup>2</sup> a wide hiatus<sup>3</sup> and severe reflux<sup>4</sup> remains controversial, however. Furthermore, the question of durability remains unanswered and uncertainty exists as to the best form of operative procedure, including mesh repair of the hiatus.

Composite fundoplication has been performed by the senior author (GLF) since 2009, in an attempt to improve recurrence. The principles of the operation include extensive mediastinal dissection to mobilise the oesophagus, repair of the hiatus with deep sutures through the fascial component of the crural pillars, a 360° fundoplication and posterior cardioplexy.<sup>5</sup>

Early outcome (at a mean of 574 days following surgery) of the first 100 consecutive cases was published in 2015.<sup>6</sup> In that

study, objective follow-up review was achieved in 97% of patients at four months. Early recurrence was observed in nine cases (2 large, 7 small hernias) and reoperation in two. QoL scores were significantly improved after surgery ( $p<0.0001$ ). The modified Visick score<sup>7</sup> fell from a median of 3.0 to 1.7. The mean Gastrointestinal Quality of Life Index (GIQLI)<sup>8</sup> improved from 87.8 (standard deviation [SD]: 24) preoperatively to 109.1 (SD: 22). There was evidence ( $p=0.03$ ) that the mean GIQLI score in patients with recurrence (94, SD: 24.6) was worse than in those without recurrence (110, SD: 21.8).

This paper describes the same cohort now at a mean of 1,207 days (SD: 260 days) following surgery. Outcome measures were QoL, hernia recurrence, reoperation and postoperative oesophagitis.

## Methods

A prospective database of the first 100 patients undergoing composite repair has been maintained on Access® (Microsoft, Redmond, WA, US). The cohort was verified and 4 patients in the 100 reported previously<sup>6</sup> violated protocol: There was one duplication and overestimation of hernia size in three patients. These patients were replaced by the next sequential patients in the cohort. Consent to further follow-up review was withdrawn by five patients (2 psychogeriatric diagnoses, 2 with frailty, 1 refusal for further tests) but reporting of existing results was permitted.

Age, sex, body mass index (BMI) and ASA (American Society of Anesthesiologists) grade were recorded. The size of the hernia was estimated during the operation, according to established criteria. Operative variables were the number of sutures in the hiatal repair and whether there was perceived tension on the hiatus during closure. Tension was assessed by the senior author (GLF), based on substantial operative experience, as pressure required to gain apposition of the crural pillars. Details were recorded in a standardised proforma and transferred to the database.

Hernia size was estimated by a combination of radiological and intraoperative assessment, and was expressed by the percentage of stomach in the mediastinum. The landmarks used at laparoscopy were the pylorus (100% herniation), crow's foot (75%) and a point halfway between the crow's foot and angle of His (50%). The size of the hiatus was classified by surgical estimation as moderately large, large or very large.

## Review process

Mail review and phone interviews were used to assess QoL by GIQLI, the modified Visick score and the Dakkak score for dysphagia.<sup>9</sup> GIQLI comprises a 144-point scale based on 56 questions. The modified Visick scale has four categories: grade 1 (no symptoms), grade 2 (minimal symptoms, no lifestyle changes), grade 3 (significant symptoms requiring lifestyle changes and medical consultation) and grade 4 (severe or recurrent symptoms interfering with enjoyment of life). The Dakkak dysphagia score has a range of 0 (severe dysphagia) to 45 (normal swallowing), based on nine questions. While GIQLI and the modified Visick score were shown to improve significantly after surgery in the initial report, no comparison was made of dysphagia scores.<sup>6</sup>

Early (within 12 months) and later (after 12 months) postoperative QoL scores were compared to establish the durability of symptom improvement. Paired and unpaired comparisons were made of the initial GIQLI, modified Visick and dysphagia scores from the first year after surgery with the most recent scores. Scores at later postoperative follow-up review were also compared with preoperative scores.

Paired analysis of QoL was also carried out in the recurrence subgroup. Two comparisons were made. First, GIQLI, modified Visick and dysphagia scores were compared prior to and after surgery but before recurrence was noted. Second, postoperative scores were compared before and after recurrence.

Anatomical follow-up review was predominantly with endoscopy. This took place at least once in the first year after surgery and was then planned every 2–3 years thereafter. The presence of a recurrent hernia, oesophagitis (on endoscopy), Barrett's oesophagus (on endoscopy and histology) and gastric residue was noted. Where endoscopy was impractical, patients undertook a barium meal and the radiographs were obtained for review.

Recurrence was categorised as a hernia of either <2cm or >2cm of intrathoracic stomach, measured vertically from the hiatus. Three types of recurrence were noted (Fig 1). Telescoping recurrence occurred when the gastro-oesophageal junction (GOJ) slipped through the fundoplication, which remained below the diaphragm itself. Hiatal failure arose when the GOJ and fundoplication herniated through the hiatus. Finally, paraoesophageal recurrence was identified when there was herniation of the stomach into the mediastinum, with the GOJ remaining in the abdomen.<sup>10</sup>

## Statistical analysis

SPSS® version 21 (IBM, New York, US) was used for analysis. Nonparametric data were analysed with the related samples Wilcoxon signed-rank test. Parametric data were analysed with the paired t-test. Unpaired data were compared with the independent samples t-test and Mann–Whitney U test. Time to recurrence and median follow-up were analysed using Kaplan–Meier and reverse Kaplan–Meier methods.<sup>11</sup> Covariates were analysed with the Cox proportional hazards model. Multivariate regression was carried out if the *p*-value was ≤0.1 on univariate regression. Statistical significance was accepted at *p*<0.05.

## Results

The mean patient age at the most recent review was 71 years (SD: 10.2 years) and 71 patients were female. Other patient variables are described in the initial report<sup>6</sup> and in Table 1. One postoperative mortality was described in the initial report. Since then, a further patient died of causes unrelated to surgery.

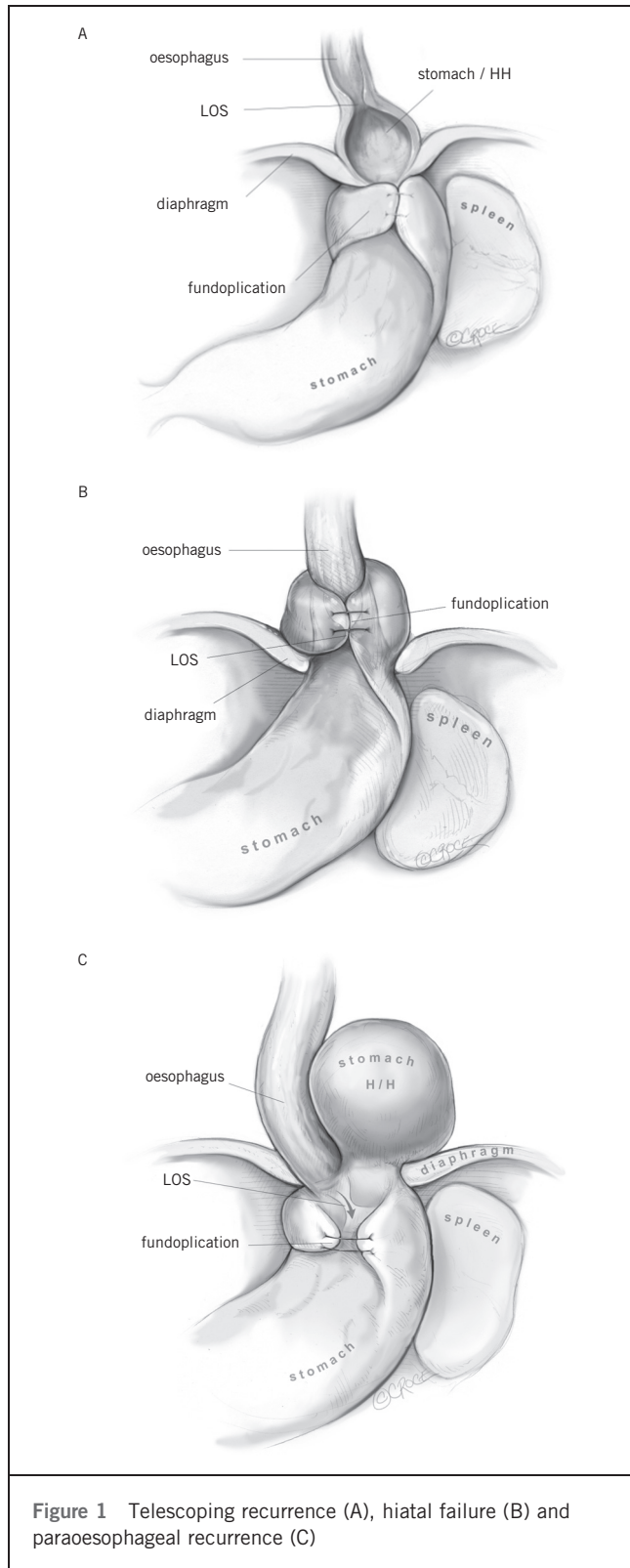
### Hernia recurrence

Ninety-seven patients (97%) underwent anatomical review at a median of 24 months (95% confidence interval [CI]: 20–28 months) following surgery. A recurrent hernia was found in 24 patients (24%). Five (5%) were larger than 2cm. Hiatal failure occurred in 13, telescoping recurrence in 9 and paraoesophageal recurrence in 2 patients (Table 2). The median time to recurrence was 40 months (95% CI: 34–46 months).

### QoL: early postoperative vs later postoperative scores

Early follow-up scores were recorded at a median of 2 months (range: 1.0–11.9 months) and later review was at a median of 27 months (range: 12.0–51.6 months). There was an 85% response rate to QoL follow-up.

Paired QoL data for GIQLI were available in 70 patients. The mean GIQLI score was 107 (SD: 20.5) at early follow-up review and 109 (SD: 21.5) at later review. There was no evidence of a significant change between periods (mean



**Table 1** Patient characteristics

Characteristic	Number	Missing data
Mean age at follow-up (years)	72.0 (SD: 10.2)	0%
Patients with tension on completed hiatal repair	6	14%
Size of hiatus: moderate / large / very large	11 / 69 / 14	6%
Mean number of hiatal sutures	3.8 (SD: 0.82)	6%
Body mass index (kg/m <sup>2</sup> )	29 (range: 20–44)	30%
ASA grade: 1 / 2 / 3 / 4	4 / 38 / 27 / 2	29%
Size of hernia (% in mediastinum)	75% (range: 20–100%)	6%

SD = standard deviation; ASA = American Society of Anesthesiologists

**Table 2** Size and type of recurrent hiatal hernias

Type of recurrence	Recurrence <2cm	Recurrence >2cm	Total
Hiatal failure	9	4	13
Telescoping	8	1	9
Paraoesophageal	2	0	2
<b>Total</b>	<b>19</b>	<b>5</b>	<b>24</b>

difference: -2.4, 95% CI: -6.7–2.0,  $t=-1.09$ ,  $df=69$ ,  $p=0.279$ ). Paired Visick scores were available in 66 patients. The median modified Visick score was 2 (range: 1–4) at both early and later follow-up review ( $p=0.954$ ). Paired dysphagia scores were available in 65 patients. The median dysphagia score at early follow-up review was 41 (range: 8–45) and at later review, it was also 41 (range: 10–45). This was not significantly different ( $p=0.623$ ). Unpaired data analysis yielded similar results (Tables 5 and 4).

**QoL: preoperative vs later postoperative scores**

The mean preoperative GIQLI score was 89 (SD: 24.6) ( $n=90$ ), improving to 108 (SD: 21.6) ( $n=84$ ) at later postoperative review ( $p<0.001$ ). The median preoperative modified Visick score was 3 (range: 1–4) ( $n=84$ ) and improved to 2 (range: 1–4) ( $n=82$ ) at later postoperative review ( $p<0.001$ ). The median preoperative dysphagia score was 35 (range: 1–45) ( $n=85$ ) while the median later postoperative score was 30 (range: 10–45) ( $n=81$ ) ( $p=0.072$ ).

**QoL after hernia recurrence**

Table 5 shows paired analyses of QoL scores for the 24 patients who developed recurrent hernias. GIQLI (paired data available for 18 patients) improved significantly after

**Table 3** Quality of life scores (paired analysis)

Indicator	Early postoperative	Later postoperative	p-value
Mean GIQLI (n=70)	107 (SD: 20.3)	109 (SD: 21.3)	0.279*
Median Visick score (n=66)	2 (1–4)	2 (1–4)	0.954**
Median dysphagia score (n=65)	41 (8–45)	40.5 (10–45)	0.623**

GIQLI = Gastrointestinal Quality of Life Index; SD = standard deviation  
\*paired t-test; \*\*related samples Wilcoxon signed-rank test

surgery from a mean score of 92 to 108 (p=0.004). After recurrence, the mean GIQLI score remained 106. This was not significantly different from the mean GIQLI score prior to recurrence (p=0.089). The modified Visick score (paired data available for 15 patients) improved from a median of 4 preoperatively to 2 after surgery (p=0.001). After recurrence, it remained at a median of 2 (p=0.539). The median dysphagia score (paired data available for 16 patients) prior to surgery was 35. There was no evidence to suggest this changed after surgery (median: 37, p=0.507) or after recurrence (median: 45, p=0.445).

Using Cox multivariate regression analysis, recurrence was found to be significantly more likely in patients older than 70 years at surgery (hazards ratio [HR]: 5.0, 95% CI: 1.2–7.4, p=0.017) and also where the surgeon noted there was tension on the completed hiatal repair (HR: 4.1, 95% CI: 1.1–14.7, p=0.032) (Table 6). Tension on hiatal repair was considered present in six patients and three (50%) developed recurrences. Recurrence occurred in 16 (34%) of the 47 patients over the age of 70 years.

**Oesophagitis, Barrett’s oesophagus and delayed gastric emptying**

Oesophagitis occurred in five patients (5%) following surgery, two having a recurrent hernia at the time of diagnosis. Barrett’s oesophagus was noted in 27 patients (27%). Gastric residue was found in 19 cases (19%) on endoscopy despite an overnight fast.

**Discussion**

Low morbidity and reoperation rates and sustained improvement to QoL are predictable outcomes following GHH repair. Overall QoL and reflux outcomes were sustained at two years. The hernia recurrence rate (24%) was comparable with those in other series with routine objective follow-up.<sup>12,15</sup> Reoperation (3%) was less frequent than in these studies.

**Table 4** Quality of life scores (unpaired analysis)

Indicator	Preoperative	Early postoperative	Later postoperative	p-value, preoperative vs early postoperative	p-value, early vs later postoperative	p-value, preoperative vs later postoperative
Mean GIQLI	89 (SD: 24.6) n=90	106 (SD: 20.3) n=84	108 (SD: 21.6) n=84	<0.001	0.557	<0.001
Median Visick score	3 (range: 1–4) n=84	2 (range: 1–4) n=81	2 (range: 1–4) n=82	<0.001	0.586	<0.001
Median dysphagia score	35 (range: 1–45) n=85	41 (range: 4–45) n=80	39 (range: 10–45) n=81	0.051	0.836	0.065

GIQLI = Gastrointestinal Quality of Life Index; SD = standard deviation

**Table 5** Quality of life scores after recurrence in 24 patients (paired analysis)

Indicator	Preoperative	Postoperative, before recurrence	Postoperative, after recurrence	p-value, preoperative vs after recurrence	p-value, before recurrence vs after recurrence
Mean GIQLI (n=18)	92 (SD: 21)	108 (SD: 11)	106 (SD: 20)	0.004*	0.089*
Median Visick score (n=15)	4 (range: 2–4)	2 (range: 1–4)	2 (range: 1–4)	0.001**	0.339**
Median dysphagia score (n=16)	33 (range: 9–45)	37 (range: 15–45)	45 (range: 10–45)	0.507**	0.445**

GIQLI = Gastrointestinal Quality of Life Index; SD = standard deviation  
\*paired t-test; \*\*related samples Wilcoxon signed-rank test

Table 6 Factors for risk of recurrence

Characteristic	p-value	
	Univariate regression	Multivariate regression
Age >70 years	0.020	0.017 (HR: 3.0, 95% CI: 1.2–7.4)
Tension in hiatal closure	0.050	0.032 (HR: 4.1, 95% CI: 1.1–14.7)
ASA grade ≥3	0.22	
Type IV hernia	0.29	
Body mass index >30kg/m <sup>2</sup>	0.48	
Hiatal size 'very large'	0.53	
Hernia size ≥75%	0.65	
Male sex	0.72	
≥4 stitches in hiatus	0.97	

HR = hazard ratio; CI = confidence interval; ASA = American Society of Anesthesiologists

Endoscopic surveillance suggested oesophagitis was uncommon in our cohort (5%) compared with other large series.<sup>14,15</sup> In contrast to this, the prevalence of gastroparesis (as evidenced by the presence of gastric contents after fasting for endoscopy) was higher among our patients (19%). This parameter has not been reported well in other studies, however, and is therefore an avenue for further research.

Age >70 years and estimated tension were the only predictors of recurrence. Data for some cases were missing for tension (16%), BMI (29%) and ASA grade (30%). Conversely, it has been reported that younger and obese patients are more likely to experience recurrence.<sup>12</sup> However, the series are not comparable owing to differences in age (69 vs 63 years) and weight loss between the study cohorts.

During operations where tension was noted ( $n=7$ ), the pneumoperitoneum was reduced to 8mmHg and the liver retractor was loosened to assist in the recruitment of the left diaphragm. It may be worth selecting this subgroup of patients for further measures to prevent recurrence. Releasing incisions in the diaphragm may be utilised<sup>15</sup> or mesh.<sup>5,16</sup>

Routine use of biological mesh in a large randomised controlled trial (RCT) did not show a reduction in the incidence of recurrence.<sup>17</sup> Another very small RCT of mesh in patients with large (8cm) hiatal defects did show a significant reduction in recurrence (0% vs 20% at 40 months).<sup>16</sup> This was perhaps an inverse finding because the 'no mesh' group results were poor. The efficacy of mesh buttressed repair remains uncertain. Reoperation was required in 3% of our cases so only a small proportion of patients treated with mesh may benefit. On the other hand, if mesh were used routinely, the risk of mesh related complication would be present in 97%.

The prospective studies of primary mesh hiatus repair reported no complications at long-term follow-up.<sup>18–21</sup> Nevertheless, reoperation was noted to be highly morbid, major resection at revision being required frequently. Recurrent hernias appear to be largely asymptomatic<sup>12,15,17,22–24</sup> and did not affect QoL in our series.

The reporting of recurrence has not been standardised, some not reporting recurrence of <2cm.<sup>17</sup> Using such criteria, our series would have a recurrence rate of only 5%. Other series only report symptomatic (ie not objective) recurrence, leading to difficult comparison.<sup>25,26</sup>

Recurrence in this cohort affected QoL at early follow-up review but not later. Early and later recurrence may have a different symptom profile or severity. Large recurrence had been detected in two patients by four months<sup>6</sup> and has been observed in five further patients since then. Two reoperations were performed during the study period of the initial report<sup>6</sup> and only one reoperation has been carried out during the later follow-up period. This difference was not significant but may represent different causation. The natural history of small recurrence is not known but it is possibly benign.<sup>27</sup>

Compared with preoperative scores, overall QoL and reflux scores remained significantly improved at 27 months, consistent with other reports of GHH repair.<sup>10,12,13</sup> Both the GIQLI and modified Visick scores improved, and did not change over time despite 24% of patients developing recurrence. Symptomatic outcome therefore appears durable.

Dysphagia has been assessed in two studies after surgery, using different reporting techniques and methodology.<sup>12,13</sup> Aly *et al* performed massive hiatus hernia repair without mesh, using posterior cardiopexy and predominantly 360° fundoplication in 100 patients.<sup>12</sup> At four years, 23% of patients developed recurrence, with 10% of all patients developing recurrence of >2cm and 7% having reoperation for recurrence or dysphagia. Dysphagia was recorded using a ten-point scale and was examined in a subgroup of patients who had significant preoperative dysphagia. In these 51 patients, the dysphagia scores improved from 6.1 to 1.5 ( $p<0.001$ ). The analysis was different from that in our study and the results are therefore not comparable.

Andujar *et al* compared QoL in 166 patients with GHHs repaired without mesh, predominantly by 360° fundoplication (8.4% had gastropexy only).<sup>15</sup> Recurrent hernias were found in 25% of cases (5% large) but symptoms remained improved at 24 months. Early reoperation (7 months) was performed in 6% of patients.

A 360° fundoplication was chosen in this series as partial fundoplication has been associated with recurrent reflux.<sup>28</sup> Nevertheless, total fundoplication can be associated with a higher rate of reoperation<sup>28</sup> and dysphagia.<sup>29</sup> The three reoperations in this series, however, were for larger recurrences with resultant dysphagia. Barium swallow in these patients showed acute angulation at the GOJ, perhaps peculiar to the cardiopexy technique.

Oesophagitis was uncommon (5%), reflecting the use of total fundoplication. Poor gastric emptying is known to be associated with hiatal hernia.<sup>30</sup> Longer follow-up study is needed to assess whether postoperative food retention is a

temporary phenomenon related to surgery and vagal dysfunction or a permanent phenomenon.

The prevalence of Barrett's oesophagus was 27%. This confirms observations that there is a strong association between hiatal hernia and Barrett's oesophagus,<sup>51–55</sup> and suggests that endoscopy would be wise in this group of patients.

## Conclusions

The composite fundoplication-cardiopexy technique led to sustained improvements at a median of 1,207 days in overall QoL and reflux but not dysphagia. Recurrence was predominantly small and relatively asymptomatic, the rates were comparable with those in other reports and reoperation was required infrequently. Patients with a recurrent hernia had symptoms similar to those with anatomically intact repairs. The risk factors of older age and tension in the repair may lead to consideration of alternative selective approaches to surgery in this small subgroup; however, it is unknown whether this would significantly affect reoperation rates. These figures cannot support a routine repair with mesh but perhaps a tailored approach could be evaluated for an identifiable higher risk group.

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