

Comparison between Rapid Rhino® Pack and Gloved Nasal Pack as Middle Meatal Spacers after Endoscopic Sinus Surgery

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ABSTRACT

Background: Rapid Rhino® nasal pack was used to minimize bleeding and to relieve postoperative pain after endoscopic sinus procedures (ESS), while different nasal packs have been employed in various sinonasal surgeries throughout the last decades. The aim of the study was to compare the effectiveness of Rapid Rhino® Pack and Gloved Nasal Pack as Middle Meatal Spacers after ESS for reducing postoperative adhesion in-patient undergoing ESS and reducing the pain during pack removal.

Patients and Methods: We conducted a prospective, randomized controlled clinical trial, at ENT Department, Faculty of Medicine, at Zagazig University Hospitals on 44 cases. Patients were randomized to receive Rapid Rhino® pack the in one middle meatus (right or left), and the Gloved Nasal pack in the contra-lateral middle meatus intra-operatively.

Results: Sino-nasal Outcome Test (SNOT-22) chart significantly decreased from a pre-operative mean of 52.59 (SD13.17) to 34.18 (SD 8.79) at 3 months post-operatively. Visual Analogue Scale (VAS) for pain significantly decreased in the Rapid Rhino pack groups compared with gloved nasal pack. Bleeding was more in gloved nasal pack side with statistically significant difference among both groups ($p=0.007$). Endoscopic evaluation of our cases revealed no significant difference between both groups regarding edema, discharge and both groups were significantly improved while significant differences were found regarding while scarring and crusting.

Conclusion: We concluded that whether packs are always necessary following endoscopic sinus surgery. Rapid Rhino® Pack fulfils their primary purpose of hemostasis and is well tolerated. It has also been shown to cause little pain on removal and may prevent adhesion formation.

Keywords: Rapid Rhino® Pack, Nasal Pack, Endoscopic Sinus Surgery, Zagazig University, randomized controlled clinical trial, Visual Analogue Scale, Sino-nasal Outcome Test.

INTRODUCTION

With respect to nasal and sinus anatomy, the middle turbinate serves as a link between the superior and inferior turbinate structures. For starters, the nasal septum and the inferior turbinate form an important triangle structure in the nasal cavity that might impair functional breathing. Second, the osteomeatal complex, which includes the middle turbinate, uncinate process, and ethmoid bulla, is a tiny triangular structure in the upper nasal cavity that might interfere with sinus outflow. Olfactory clefts are also formed by the nasal septum and midturbinate, which alter the perception of smell ⁽¹⁾.

There are numerous roles linked with the nasal cavity's middle turbinate, including, upper airway humidification, olfaction, airflow regulation, lubrication, as well as temperature management, and filtration ⁽²⁾.

After endoscopic sinus procedures (ESS), adhesions commonly occur between the middle turbinate and the lateral nasal wall. Many patients who have these adhesions end up needing revision surgery, and it's not uncommon ⁽³⁾. Following ESS, a middle meatal spacer may help decrease adhesions ⁽⁴⁾.

Displacement, aspiration, and discomfort have been related with the use of removable middle meatal splints, which are generally helpful at lowering adhesion rates ⁽⁴⁾. Various nasal packs have been

utilized in the previous decades for a variety of sinonasal procedures, The optimal nasal pack should be hemostatic, painless, and cause the least amount of harm to the nasal mucosa during insertion and removal ⁽⁵⁾.

It is common to see scarring and synechia as a result of standard nasal packing despite the fact that hemostasis has been achieved. This is a significant contributor to postoperative morbidity ⁽⁶⁾. Postoperative discomfort and bleeding after endoscopic sinus procedures were significantly reduced in studies conducted with the Rapid Rhino® nasal pack ⁽⁷⁾.

For use following endoscopic sinus surgery, Rapid Rhino Riemann® was specifically developed. polyvinyl chloride (PVC) wraps around a polyurethane foam core. As soon as it's wet, it transforms into a gel-like substance. To aid in the healing process, it maintains the wound wet while also allowing for simple removal without damaging the healing tissues. Reinforced knitted carboxymethylcellulose CMC fibres are used to make up the fabric coat. Post-operative adhesion development can be reduced by CMCs, according to research. Platelet aggregation and blood clotting are promoted by the release of calcium chloride from CMCs ⁽⁸⁾.

The aim of the study was to compare the effectiveness of Rapid Rhino® Pack and Gloved Nasal Pack as Middle Meatal Spacers after ESS for reducing

postoperative adhesion in-patient undergoing ESS and reducing the pain during pack removal.

PATIENTS AND METHODS

At Oto-Rhino-Laryngology department of Zagazig University hospital, 44 patients (88 nasal cavities), with bilateral CRS, with or without sinonasal polyp, who underwent ESS were studied in a prospective randomized controlled clinical trial.

Inclusion criteria:

Age group; 15-60 years of age, all patients had CT-confirmed inflammatory sinus disease with Lund-Mackay scores ranging from 6 to 24, and no previous history of endoscopic sinus surgery

Exclusion criteria:

Resected middle turbinate, patients less than 15 and more than 60, all patients had Lund-Mackay scores below 6, patients who had already undergone ESS (revision case) or any other endoscopic rhinological operative intervention, known cases of primary immunodeficiency, and sinonasal malignancy.

All patients were subjected to:

1. A thorough review of the patient's medical history. A standard visual analogue scale (VAS) was used to assess subjectively the severity of nasal obstruction and the associated nasal symptoms such as rhinorrhea and sneezing.
2. Complete ENT examination including anterior rhinoscopy and nasal endoscopy.

Sino nasal outcome test (SNOT-22) questionnaire :

Validated self-administration of the SNOT-22 is required for the evaluation of CRS patients. They're divided into five categories: "no difficulty at all," "worst potential symptom," and "everything in between." In general, larger SNOT-22 total scores indicate more severe symptoms and can vary anywhere from 0 to 110. The SNOT-22 total score has been found to have good psychometric qualities. SNOT-22 was translated into Arabic and validated in the current investigation ⁽⁹⁾.

Diagnostic nasal endoscopy:

All patients were given a diagnostic nasal endoscopy during their initial outpatient clinic visit, and the results were documented. The endoscopic finding was scored using the Lund-Kennedy

endoscopic appearance score, which assigns one of the following scores: 0, 1, 2, or 3: It is possible to have zero polyps, one polyp exclusively in the MM, and two polyps outside of the MM, but not fully obstructing the nose. Edema levels range from 0 (no swelling) to 2 (moderate to severe). Discharge; zero is a clear, one is thin discharge and two is a thick purulent discharge.

CT Scan: View from above after exhausting all medicinal options, a bone window and no contrast CT scan of the nose and paranasal sinuses was performed.

The Lund-Mackay staging system (ease and dependability) was utilized for staging ⁽¹⁰⁾.

Operative procedure:

A general anaesthetic was used for all of the surgeries. Placards with 0.5% oxymetazoline were put in the nose and middle meatus for 10 minutes. An uncinectomy, a middle meatal antrostomy, and an anterior and posterior ethmoidectomy were all incorporated in the FESS by Messer Klinger/Stamberger procedure. The extent of each patient's sinus surgery was determined by the severity and location of their condition, however all of the patients in the study had a middle meatal antrostomy and an anterior ethmoidectomy performed on them. An endoscopic septoplasty was used when septal deviation was obstructing access to the middle meatus.

If possible, we tried to save as much of the middle turbinate mucosa in its original state, as well as its horizontal basal lamella, in order to prevent it from adhering laterally.

To decide whether middle meatus (right or left) received the RapidRhino® pack, a coin toss was used, and the contra-lateral middle meatus received the Gloved Nasal pack, which was randomised by a coin flip. When the RapidRhino® pack was inserted at the end of the surgery, the patients were under general anaesthesia and were unable to tell the difference between the packing on each side. Once the RapidRhino® pack was in place, a digital snapshot of the spacer was taken for each patient.

For insertion, the Rapid Rhino Riemann® was moistened in sterile water for 30 seconds before use (Smith & Nephew Medical Limited, Heslington, UK). Rapid Rhino Riemann® (3cm) was gripped with forceps and inserted gently until the entire piece was positioned into the right or left MM according to randomization and a gloved nasal pack was placed into the other side under endoscopic vision.



Figure (1): Rapid Rhino Riemann® (Smith&Nephew Medical Limited, Heslington, UK) 3cm.



Figure (2): A piece of Rapid Rhino Riemann® putting in sterile water before insertion.



Figure (3): Right middle meatus after insertion of Rapid Rhino Riemann (S=septum, MT= Middle turbinate, RR = Rapid Rhino Riemann). All patients were subjected to the same follow-up schedule after 2, 6, 12 weeks postoperatively and in

each visit. Evaluation of patients was done by subjective evaluation using VAS, objective evaluation including endoscopic and C.T examination, SNOT Questionnaire, as well as Endoscopic score.

Ethical consent:

Research ethics council at Zagazig University approved the study (ZU-IRB #7081) as long as all participants provided informed consent forms. Ethics guidelines for human experimentation were adhered to by the World Medical Association's Helsinki Declaration.

Statistical analysis:

In order to analyze the data acquired, Statistical Package of Social Science (SPSS) version 20 was used to execute it on a computer. In order to convey the findings, tables and graphs were employed. The quantitative data was presented in the form of the mean, median, standard deviation, and confidence intervals. The information was presented using qualitative statistics such as frequency and percentage. The student's t test (T) was used to assess the data while dealing with quantitative independent variables. Pearson Chi-Square and Chi-Square for Linear Trend (X²) were used to assess qualitatively independent data. The significance of a p value of 0.05 or less was determined.

RESULTS

Mean age was distributed as 33.63 (SD 12.01) years and ranged between 15 and 65. Regarding gender distribution, males were 54.5% and females were 45.5%. The majority of pre-operative diagnosis (77.3%) was bleeding nasal polyps (BNP), then chronic sinusitis (18.2%) then BNP and deviated nasal septum (DNS) (4.5%) (Table 1).

Table (1): Characteristics of the studied group.

| Age | | | |
|----------------|---|--------------|-------|
| Mean± SD | | 33.63±12.01 | |
| Median (Range) | | 34.0 (15-65) | |
| | | N | % |
| Sex | Female | 20 | 45.5 |
| | Male | 24 | 54.5 |
| | Total | 44 | 100 |
| Diagnosis | Bleeding nasal polyps | 34 | 77.3 |
| | Chronic sinusitis | 8 | 18.2 |
| | bleeding nasal polyps and deviated nasal septum | 2 | 4.5 |
| | Total | 44 | 100.0 |

Number of surgical packs used among studied group is shown in (Table 2)

Table (2): Number of surgical packs used among studied group.

| Variable | Rapid rhino | | Gloved nasal | |
|------------|-------------|------|--------------|------|
| | N | % | N | % |
| Right side | 20 | 45.5 | 24 | 54.5 |
| Left side | 24 | 54.5 | 20 | 45.5 |

Visual Analogue Scale (VAS) for pain was reported in both groups at 6 hour from inserted packs and after pack removal and pain was significantly less in the Rapid Rhino pack group (Table 3).

Table (3): Visual Analogue Scale (VAS) for evaluation of nasal pain after 6 hours and after removal of pack

| Variable | Rapid Rhino | Gloved Nasal | Mann-Whitney U test | P value |
|--|----------------------|----------------------|---------------------|---------|
| VAS 6 H Median (Range) | 3.81±1.56 3 (2-7) | 6.54±1.92 6 (3-9) | 3.12 | 0.00** |
| VAS after removal of pack Median (Range) | 2.01±0.74 0 (0-3) | 4.28±1.01 3 (0-4) | 2.82 | 0.00** |
| P value | 0.00** | 0.00** | | |

Bleeding was more in gloved nasal pack side with statistical significant difference among both groups (p=0.007) (Table 4).

Table (4): Bleeding score distribution after packing remove.

| Variable | | Group | | X ² | P value | |
|----------|------|-------------|--------------|----------------|---------|-------|
| | | Rapid Rhino | Gloved Nasal | | | |
| Bleeding | 0.00 | N | 22 | 11.1 | 0.007 | |
| | | % | 50% | | | 36.4% |
| | 1.00 | N | 20 | | | 14 |
| | | % | 45.5% | | | 31.8% |
| | 2.00 | N | 2 | | | 14 |
| | | % | 4.5% | | | 31.8% |
| Total | | N | 44 | 44 | | |
| | | % | 100% | 100% | | |

Post-operative endoscopic evaluation for polyps showed no significant difference between groups and both groups were significantly improved (Table 5).

Table (5): Comparison between the 2 groups for the incidence of post-operative polyps.

| Variable | | Group | | X ² | P value |
|----------------|------|-------------|--------------|----------------|---------|
| | | Rapid Rhino | Gloved nasal | | |
| Polyp 2 Weeks | 0.00 | N | 44 | 44 | ----- |
| | | % | 100% | 100% | |
| | 1.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| | 2.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| Polyp 6 Weeks | 0.00 | N | 40 | 44 | 0.58 |
| | | % | 90.9% | 100% | |
| | 1.00 | N | 4 | 0 | |
| | | % | 9.1% | 0.0% | |
| | 2.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| Polyp 3 Months | 0.00 | N | 40 | 44 | 0.58 |
| | | % | 90.9% | 100% | |
| | 1.00 | N | 4 | 0 | |
| | | % | 9.1% | 0.0% | |
| | 2.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| Total | | N | 44 | 44 | |
| | | % | 100% | 100% | |

Post-operative follow up for edema showed no significant difference between groups and both groups were significantly improved (Table 6).

Table (6): Comparison between the 2 groups for the incidence of post-operative edema.

| Variable | | Group | | X ² | P- value |
|----------------|------|-------------|--------------|----------------|----------|
| | | Rapid Rhino | Gloved Nasal | | |
| Edema 2 Weeks | 0.00 | N | 26 | 26 | 0.0 |
| | | % | 59.1% | 59.1% | |
| | 1.00 | N | 14 | 14 | |
| | | % | 31.8% | 31.8% | |
| | 2.00 | N | 4 | 4 | |
| | | % | 9.1% | 9.1% | |
| Edema 6 Weeks | 0.00 | N | 42 | 42 | 0.00 |
| | | % | 95.5% | 95.5% | |
| | 1.00 | N | 2 | 2 | |
| | | % | 4.5% | 4.5% | |
| | 2.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| Edema 3 Months | 0.00 | N | 44 | 44 | 0.00 |
| | | % | 100% | 100% | |
| | 1.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| | 2.00 | N | 0 | 0 | |
| | | % | 0.0% | 0.0% | |
| Total | | N | 44 | 44 | |
| | | % | 100% | 100% | |

Post-operative follow up for discharge showed no significant difference between groups and both groups were significantly improved (Table 7).

Table (7): Comparison between the 2 groups for the incidence of post-operative discharge.

| Variable | | | Group | | X ² | P value |
|-----------------------|------|---|-------------|--------------|----------------|---------|
| | | | Rapid Rhino | Gloved nasal | | |
| Discharge 2 Weeks | 0.00 | N | 0 | 0 | 3.85 | 0.072 |
| | | % | 0.0% | 0.0% | | |
| | 1.00 | N | 42 | 34 | | |
| | | % | 95.5% | 77.3% | | |
| | 2.00 | N | 2 | 10 | | |
| | | % | 4.5% | 22.7% | | |
| Discharge 6 Weeks | 0.00 | N | 12 | 6 | 2.11 | 0.34 |
| | | % | 27.3% | 13.6% | | |
| | 1.00 | N | 32 | 39 | | |
| | | % | 72.7% | 81.8% | | |
| | 2.00 | N | 0 | 2 | | |
| | | % | 0.0% | 4.5% | | |
| Discharge 3 Months | 0.00 | N | 8 | 6 | 0.35 | 0.62 |
| | | % | 18.2% | 13.6% | | |
| | 1.00 | N | 36 | 38 | | |
| | | % | 81.8% | 86.4% | | |
| | 2.00 | N | 0 | 0 | | |
| | | % | 0.0% | 0.0% | | |
| Total | | N | 44 | 44 | | |
| | | % | 100% | 100% | | |

Post-operative follow up for scaring showed significant increase in post-operative scaring level among sides with gloved nasal pack than other sides and both groups were significantly improved (**Table 8**).

Table (8): Comparison between the 2 groups for the incidence of post-operative scaring.

| Variable | | | Group | | X ² | P value |
|---------------------|------|---|-------------|--------------|----------------|---------|
| | | | Rapid Rhino | Gloved nasal | | |
| Scaring 2 Weeks | 0.00 | N | 32 | 20 | 6.77 | 0.03 |
| | | % | 72.7% | 45.5% | | |
| | 1.00 | N | 12 | 22 | | |
| | | % | 27.3% | 50% | | |
| | 2.00 | N | 0 | 2 | | |
| | | % | 0.0% | 4.5% | | |
| Scaring 6 Weeks | 0.00 | N | 36 | 20 | 8.12 | 0.01 |
| | | % | 81.8% | 45.5% | | |
| | 1.00 | N | 8 | 20 | | |
| | | % | 18.2% | 45.5% | | |
| | 2.00 | N | 0 | 4 | | |
| | | % | 0.0% | 9.1% | | |
| Scaring 3 Months | 0.00 | N | 40 | 30 | 6.55 | 0.02 |
| | | % | 90.9% | 68.2% | | |
| | 1.00 | N | 4 | 13 | | |
| | | % | 9.1% | 29.5% | | |
| | 2.00 | N | 0 | 1 | | |
| | | % | 0.0% | 2.3% | | |
| Total | | N | 44 | 44 | | |
| | | % | 100% | 100% | | |

Post-operative follow up for crusting showed significant crusting among gloved nasal sides more than other rapid rhino sides 2 weeks post-operative and after 3 months on follow up, both groups were significantly improved (**Table 9**).

Table (9): Comparison between the 2 groups for the incidence of post-operative crusting.

| Variable | | | Group | | X ² | P |
|----------------------|------|---|-------------|--------------|----------------|------|
| | | | Rapid Rhino | Gloved nasal | | |
| Crusting 2 Weeks | 0.00 | N | 26 | 22 | 6.56 | 0.04 |
| | | % | 59.1% | 50.0% | | |
| | 1.00 | N | 18 | 14 | | |
| | | % | 40.9% | 31.8% | | |
| | 2.00 | N | 0 | 8 | | |
| | | % | 0.0% | 18.2% | | |
| Crusting 6 Weeks | 0.00 | N | 38 | 30 | 2.40 | 0.31 |
| | | % | 86.4% | 68.2% | | |
| | 1.00 | N | 6 | 10 | | |
| | | % | 13.6% | 22.7% | | |
| | 2.00 | N | 0 | 4 | | |
| | | % | 0.0% | 9.1% | | |
| Crusting 3 Months | 0.00 | N | 42 | 36 | 4.06 | 0.04 |
| | | % | 95.5% | 81.8% | | |
| | 1.00 | N | 2 | 8 | | |
| | | % | 4.5% | 18.2% | | |
| | 2.00 | N | 0 | 0 | | |
| | | % | 0.0% | 0.0% | | |
| Total | | | N | 44 | | |
| | | | % | 100% | | |

DISCUSSION

An important morphological and physiological feature of the nasal cavity is the middle turbinate (MT). Olfaction, filtration, and airflow regulation are all aspects of MT's role in regulating airflow. There have been numerous MT variants described since the widespread use of the nasal endoscope and paranasal sinus computed tomography (CT) in the diagnosis of nasal and sinus infections ⁽¹¹⁾.

For the pathophysiology of sinusitis, headache, and nasal obstruction as well as endoscopic sinus and skull base surgery, the location and connection of the MT to other essential nasal structures is critical. Endoscopic sinus surgery necessitates the use of the middle turbinate, a landmark found in the ethmoidal labyrinth ⁽¹²⁾.

According to **Smith and colleagues**, ESS has changed nose and sinus surgery forever in the last quarter-century thanks to advances in endoscopic technology. When it comes to post-ESS nasal and sinus cavity treatment, there has been steady advancement in this new era. When it comes to post-operative wound care, the options range from simple bandages to complex dissolvable packs ⁽¹³⁾.

After sinus surgery, several researchers proposed that no packing should be used in the middle meatus. However, Tang also observed an 8 percent prevalence of synechia, with a 20 percent rate of those being clinically significant and negatively affecting patient reaction to the surgical procedure ⁽¹⁴⁾.

A nose pack with a spongy interior is referred to as Rapid Rhino. Riemann, Goodman, and Mannheim are just a few examples of the many types

and lengths that can be found. Carboxymethyl cellulose-coated balloons also exist (CMC). Both the balloon catheter and the spongy inner layer are coated with CMC. Nasal cavities are closed up and pressure is exerted on them by using this pack As a result, it can be considered a sort of nasal pack ⁽¹⁵⁾.

In the study of Karia and colleagues, the nylon threads put into the packs were shown to attach to the mucosa and make it difficult to remove the pack. Gel's benefits, including occlusion of harm and restoration of homeostasis, can be purchased separately as CMC (Clinical Monitoring Center). As a Sinu-Knit or Stammberger gel, it's available for purchase ⁽¹⁵⁾.

Kaur and colleagues conducted a study evaluating the gloved packing. They found that the mean VAS score for pain during the pack insertion (G.A or local anaesthesia) for gloved pack was 5.93 (SD 1.76) while during pack in situ was 3.07 (SD 0.91) and during pack removal was 3.23 (SD 1.28). Mild bleeding was observed in 11 patients during the pack removal and also mild inflammation, crusting, or adhesions were found ⁽¹⁶⁾.

Regarding all symptoms, SNOT-22 chart questionnaire was done 3 months post-operatively and the same questionnaire was used for pre-operative evaluation. SNOT-22 chart significantly decreased from a pre-operative mean of 52.59 (SD 13.17) to 34.18 (SD 8.79) at 3 months post-operatively. Visual Analogue Scale (VAS) for pain was reported in both groups at 6 hour from inserted packs and after pack removal and pain was significantly less in the Rapid Rhino pack group.

A prospective non-blinded randomized controlled trial was done by **Badran and colleagues** to evaluate the efficacy of RapidRhino® nasal pack.

It has been demonstrated to provide improved patient comfort, defined as pain while being put in place and taken out, or a nosebleed, when compared to traditional methods. People with a nosebleed or who have undergone sinus surgery can also benefit from Rapid Rhino⁽¹⁷⁾.

In a research comparing Rapid RhinoTM to similar nasal packings, Kunz and colleagues found that the Rapid RhinoTM was nearly as effective in controlling haemorrhage, but it generated substantially less discomfort and lower pain scores when inserted and removed, we found this to be in agreement with our findings⁽¹⁸⁾.

In the study of Gudziol and colleagues, the Rapid RhinoTM packing was also tested in a randomized clinical trial. Because it was less risky and painful to implant and remain in place, the Rapid Rhino packing resulted in much reduced patient discomfort overall⁽¹⁹⁾.

The results of the **Singer and colleagues** showed that the Rapid Rhino pack was equally effective at halting bleeding and easy to use. The Rapid Rhino's insertion is also less painful, according to their findings. Because it could be easily removed without recurrence of bleeding, it was preferable to regular packing. They also showed that removing the Rapid Rhino pack as soon as 24 hours after insertion was safe and feasible⁽²⁰⁾.

A study by **Celebi and colleagues** examined how long gloved packing should be left in place to obtain the desired impact of reducing surgical morbidity while also preventing synechiae, haemorrhage and septal hematoma, all without affecting patient comfort. The results of this study were in concordance with our results⁽²¹⁾.

Toxic shock syndrome and sinusitis can be avoided, as can the formation of antibiotic-resistant germs, by removing tampons as soon as possible, according to Singer and colleagues. When packings are removed early, they may increase the chance of recurrence⁽²⁰⁾.

In our study, the difference in pain scores between the two pack types was probably due to the elasticity and external gel coating of the Rapid Rhino pack, which reduces adhesion to the nasal mucosa and thus facilitates removal. The difference in bleeding was probably mostly due to the haemostatic properties of carboxymethylcellulose, and CMCs have been shown to reduce adhesion formation post-surgery⁽²¹⁾.

CONCLUSION

We concluded that whether packs are always necessary following endoscopic sinus surgery. Rapid Rhino[®] Pack fulfils their primary purpose of hemostasis and is well tolerated while in the nose. It has also been shown to cause little pain on removal and may prevent adhesion formation. Cost is an issue in national health care provision, which has to be

balanced against best possible care for the individual.

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