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Patients' perceptions and views of surgery and radio-iodine ablation in the definitive management of Graves' disease.

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Manuscripts

Title:

Patients' perceptions and views of surgery and radio-iodine ablation in the definitive management of Graves' disease.

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The main messages of the article are:

1. Most patients undergoing surgery or radio-iodine ablation for Graves' disease were involved with decision making and were satisfied with their treatment.
2. Patient involvement in the choice of definitive treatment is associated with increased satisfaction with treatment.
3. Surgery is associated with higher levels of satisfaction compared to radio-iodine.

Current research questions include:

1. Factors underlying the variation in the use of surgery and radio-iodine need to be explored.
2. The long term effectiveness and quality of life after definitive treatment of Graves' disease is unknown

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Conflict of interest or financial interest: – nothing to declare.

Contributorship Statement:

JH – Design, data collection, analysis.

PT – data validation, analysis, draft

AA – Design, analysis.

SPB – Design, analysis.

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2
3 ABSTRACT: (195 words)
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5 Patients' perceptions and preferences influence the choice of Radioiodine ablation
6 (RIA) or surgery in the definitive management of Graves' disease. This study aimed to
7 evaluate their concerns, experiences and satisfaction following definitive treatment.
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14 A postal survey of patients who had treatment with surgery or RIA between January
15 2011 and June 2013 for Graves' disease was conducted.
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20 Of 214 patients, 136 (64%) responded. The majority of patients felt actively involved in
21 decision making (83.8%) and were satisfied (84.9%) with their treatment. Compared to
22 RIA, patients who underwent surgery were more to be satisfied with their treatment
23 (p=0.008). Discussion with the doctor was the most useful aid to decision making.
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27 Feeling involved in decision-making process was associated with improved satisfaction
28 (p<0.001).
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32 Common reasons for not choosing surgery were need for general anaesthesia, scarring
33 and voice change. Avoiding close contact, risk of persistent hyperthyroidism and
34 worsening eye disease were common reasons for not choosing RIA. Ongoing concerns
35 were hypothyroidism, scarring and eye problems after surgery and hypothyroidism and
36 eye problems after RIA.
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47 This study provides insight into patients' experiences of surgery and RIA for Graves'
48 disease and reinforces the importance of patient involvement in the decision making
49 process.
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PURPOSE OF THE STUDY

The incidence of Graves' disease is estimated at 20-50 per 100,000 patient years and is increasing (1). Management options are anti-thyroid drugs, radioiodine ablation (RIA) and surgery. Anti-thyroid drugs are usually first line treatment but up to 60% relapse (2,3). In patients who relapse, options include a further course of anti-thyroid drugs, radioiodine ablation or surgery. Both radioiodine and surgery have advantages and limitations for the patients to consider. Contraindications for surgery include pregnancy, recent neck surgery and severe, uncontrolled hyperthyroidism. Radioiodine ablation is contraindicated in pregnant or lactating women and in patients with severe eye disease. The choice of definitive treatment for Graves' disease in the absence of specific contraindications to surgery or radioiodine seems to be influenced by patient and clinician preference (4-6).

It is important to understand the reasons underlying patient preferences as well as their values, concerns and experiences with treatments received. This will enable clinicians to identify areas for improvement and help to inform future patients to facilitate decision making. Data on patients' views, concerns and satisfaction with radio-iodine and surgical treatment of Graves' disease is sparse. Patient satisfaction studies of radioiodine in the UK demonstrated that 65-87% of patients were satisfied with treatment and that just over half would recommend it to someone else (7,8). Patient reported complications included hoarseness of voice, vibrating sensation of the eyes, insomnia, forgetfulness, weight gain and depression (9). Other studies have demonstrated high satisfaction rates following surgical treatment (10,11).

The aim of this study was to evaluate patients' concerns, experiences and satisfaction with regards to both radio-iodine ablation and thyroidectomy in the definitive management of Graves' disease in a single centre.

STUDY DESIGN

A cross-sectional patient survey was conducted. All adult patients who had treatment with surgery or radio-active iodine for the management of Graves' disease diagnosed between January 2011 and June 2013 at Sheffield Teaching Hospitals NHS Foundation Trust were included. Participants were sent a postal questionnaire designed for this study. Questions regarding patients' concerns and reasons for choosing a particular treatment had predefined options as well as a free text section. Awareness of alternative treatments, involvement in the decision making process, usefulness of aids to decision making and satisfaction with treatment were explored using 5 point Likert scales. The use of radio-iodine or surgery was at the discretion of the treating endocrinologists and surgeons. Decisions were made in conjunction with patients following discussion of risks and benefits of both options.

Radio-iodine ablation

In uncomplicated Graves' disease, 400MBq to 600MBq radioiodine is given depending on the size of the thyroid gland. In patients with eye disease, prednisolone is given to prevent exacerbation 2-3 days before radio-iodine treatment and continued for 3 weeks (30 mg per day for one week, 20 mg per day for a week, and 10 mg per day for a week). Advice regarding safety precautions regarding avoidance of contact with pregnant women and young children, in addition to return to work information is provided to all patients. The treatment is provided as an outpatient and response monitored in future visits.

Surgery

Total thyroidectomy is the intended procedure in all these patients. Preoperative work up includes an anaesthetic assessment, laryngoscopy and biochemical tests to ensure a euthyroid state and a normal calcium profile. Lugol's iodine (at a dose of 0.3ml three

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3 times a day for 10 days before surgery) is routinely used to help reduce gland
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5 vascularity. In patients who have poor control of hyperthyroidism, monitored in-patient
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7 treatment with a combination of anti-thyroid drugs is carried out for 10 days before
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9 surgery. Patients are typically discharged the next day following a postoperative
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11 laryngoscopy, check of calcium levels and initiation of Thyroxine. Further follow up of
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13 thyroid biochemistry and any surgical complications is done in the surgical outpatient
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15 clinics.
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18 **Data analysis and statistics:**

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20 Descriptive data was reported as frequencies or percentages. Categorical variables were
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22 compared using the Fisher's exact test. The levels of satisfaction, as assessed by Likert
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24 scale, were compared against 'recommendation of treatment' and 'patient involvement
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26 in decision making' using the Jonckheere-Terpstra test. The level of significance was
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28 set at $p=0.05$.
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32 This survey was conducted as part of a service evaluation in relation to definitive
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34 treatment (surgery and radio-iodine) provided in Sheffield Teaching Hospitals NHS
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36 Foundation Trust and was approved by the trust's clinical effectiveness unit. As patients
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38 were approached by post several months after definitive treatment and those willing to
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40 take part in the survey did so on a voluntary basis, no additional consent process or
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42 application to ethics committee was involved. As this was a service evaluation,
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44 additional data on demographic features such as age, gender or ethnicity was not
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46 formally recorded.
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RESULTS

214 patients met the inclusion criteria. Responses were received from 136 patients (64%). 79 of 111 patients (71%) who had radio-iodine and 57 of 103 patients (55%) who had surgery responded to the questionnaire. Table 1 shows the responses to questions relating to awareness of alternative treatment options, role in decision making and satisfaction with treatment.

Decision making:

Of the 135 responders, 108 (80%) felt that they had some or detailed understanding of the alternative definitive treatment option and this was significantly more often reported in surgical patients ($p=0.007$; Fisher's exact test). 114 of 136 patients (84%) agreed or strongly agreed that they were actively involved in the decision making process. There was no significant difference between radio-iodine and surgery groups (83% vs 86%, Fishers' exact test; $p=0.443$). There was a moderate positive correlation (Spearman's $\rho=0.552$; $p<0.001$) between responses to questions about 'awareness of alternative option' and 'involvement in decision making'.

Discussion with the doctor was considered to be the most useful decision-making tool for both radio-iodine and surgical patients. 92% of patients who responded agreed that it aided their decision making. Information leaflets (55%) and discussion with friends and/or family (53%) were important to over half the patients. Over a third of patients (28/136; 37%) found the internet aided their decision making. Patients who underwent surgery were significantly more likely to report that their decision making was aided by "friends/family" ($p=0.03$; Fisher's exact test).

Satisfaction:

61/79 (80%) in the radio-iodine group and 52/57 (91%) in the surgical group were satisfied or very satisfied with their treatment (Table 1). Overall, patients who underwent surgery were significantly more satisfied with treatment compared to those that underwent radio-iodine ($p=0.008$; Fisher's exact test). When patients were asked "Would you recommend your definitive treatment to others?"; there were no statistically significant differences between the groups (72% and 77% for radio-iodine and surgery respectively). Unsurprisingly, satisfied patients were more likely to recommend their treatment to others than unsatisfied patients (Jonckheere-Terpstra test; $p<0.001$). When patients agreed to feeling involved in decision-making with regards to treatment, they were more likely to be satisfied with treatment (Jonckheere-Terpstra $p<0.001$).

Table 1. Responses to questions on awareness of alternative treatments, decision making and satisfaction with treatment received.

	Radio- Iodine	Surgery	p value
<u>"Awareness of alternative treatment option"</u>	n=79	n=56	
Not known another option was available	13 (17%)	2 (4%)	
Little understanding	8 (10%)	3 (5%)	$p=0.007^*$
Some understanding	23 (29%)	10 (18%)	
Detailed understanding	35 (44%)	40 (71%)	

Can't remember	0	1 (2%)	
<hr/>			
<u>"I was involved in decision making process"</u>	n=79	n=57	
Agreed / strongly agreed	65 (83%)	49 (86%)	
Disagreed / strongly disagreed	8 (11%)	6 (11%)	p=0.443
Unsure	6 (7%)	2 (3%)	
<hr/>			
<u>"The following helped you in decision making"</u>			
Discussion with doctor	59/67 (88%)	49/51 (96%)	p=0.18
Leaflet	28/52 (54%)	24/43 (56%)	p=1.0
Friends / Family	20/47 (43%)	27/41 (66%)	p=0.03
Internet	12/40 (30%)	16/35 (46%)	p=0.23
<hr/>			
<u>"Overall satisfaction"</u>	n=76	n=57	
Very satisfied	29 (38%)	39 (68%)	
Satisfied	32 (42%)	13 (23%)	
Neutral	9 (12%)	4 (7%)	p<0.008*
Unsatisfied	4 (5%)	1 (2%)	
Very Unsatisfied	2 (3%)	0	

<u>"Would you recommend your treatment to others?"</u>	n=76	N=56	
Yes	55 (72%)	43 (77%)	
No	3 (4%)	3 (5%)	P=0.688
Maybe	18 (24%)	10 (18%)	

Reported reasons for choice of treatment:

Table 2 lists the common reasons reported by patients for not choosing radio-iodine or surgical treatment. There were 18 different reasons given by patients who had radioiodine for not choosing to have surgery. The 'idea of general anaesthetic and surgery' was the most common (n=29) followed by scarring and voice change.

Uncommon reasons mentioned by just one patient and not listed in table 2 included having chronic obstructive pulmonary disease, not preferring inpatient stay, effectiveness of treatment, 'age', recent neck surgery, stigma of surgery (not wanting to worry friends and family) and wanting to get back to work as soon as possible. For those patients who had surgery, 15 different reasons were given for not choosing radio-iodine. Avoiding close contact with children and/or pregnant women (n=26), the risk of remaining overactive and worsening eye disease were the most common reasons.

Uncommon reasons mentioned by just one patient and not listed in table 2 included the desire to prevent recurrent eye disease, increased uncertainty regarding hormone levels,

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3 'anxiety due to exposure', being 'still over-active' despite two attempts with anti-
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5 thyroid medications.
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10 **Table 2. Common reasons for not choosing radio-iodine or surgery (in descending**
11 **order of frequency)**
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Patients who had radioiodine - reasons for not choosing surgery (n=77)	N	Patients who underwent surgery - reasons for not choosing radioiodine ablation (n=57)	N
Idea of general anaesthetic and surgery	2 9	Did not want to be away from children/pregnant women	26
Scarring	1 8	Risk of remaining overactive	25
Voice change	1 2	Did not want to avoid close contact in general	20
Pain	1 1	Worsening eye problems	17
Swallowing problems	8	Radioactive nature of the treatment	13
Told by the doctor surgery was not an option	8	Was told by the doctor that RAI was not an option	9
Hypothyroidism	5	Recommended by friends/family towards surgery	4
Recommended by friends/family towards RAI	5	Development of hypothyroidism	2
Could not take time off for the	4	Wanting to become pregnant	2

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operation			
Radio-Iodine favoured by consultant			
in clinic	4	Surgery favoured by doctor in the clinic	2
Previously 'failed thyroidectomy'	3	Did not want steroids for the eye disease	2
Other reasons each mentioned by		Other reasons each mentioned by only	
only one patient (see text for details)	7	one patient (see text for details)	4

Prior and ongoing concerns with treatment received:

Table 3 lists concerns expressed by patients relating to treatments they had actually received. 76 of 79 patients who underwent radioiodine responded to at least one of the options relating to concerns before treatment. Common concerns expressed before RIA treatment included 'avoiding close contact in general' (83%), 'radioactive nature' of the treatment (77%) and risk of 'remaining hyperthyroid' (59%). 75 of 79 patients responded to the question on ongoing concerns following RIA treatment. Common ongoing concerns included hypothyroidism (60%) and symptoms relating to the eyes (32%) and the skin (23%).

55 of 57 surgical patients responded to at least one of the issues raised in the question regarding concerns before treatment. The 'idea of general anaesthetic and surgery' (63%), voice change (62%), swallowing problems (62%), scarring (58%) and bleeding/infection (50%) were concerns for at least half of the responders. The 55 patients who responded to the question relating to concerns after surgery raised issues including 'hypothyroidism' (43%), scarring (32%) and problems with eyes (27%), swallowing (25%) and voice (23%).

Table 3. Concerns of patients (in percentage) before and after radioiodine or surgical treatment

Concerns before radioiodine	% Agreed	Concerns before surgery	% Agreed
Avoiding close contact in general	83%	Idea of general anaesthetic and surgery	63%
Radioactive nature	77%	Voice change	62%
Avoiding children/pregnant women	76%	Swallowing problems	62%
Remaining hyperthyroid	59%	Scarring	58%
Hypothyroidism	45%	Infection/bleeding	50%
Worsening eye problems	44%	Pain	48%
Other side effects	38%	Risk of hypothyroidism	39%
Preventing pregnancy/fathering	9%		
Ongoing concerns after radioiodine		Ongoing concerns after surgery	
Hypothyroidism	60%	Hypothyroidism	43%
Eye problems	32%	Scarring	32%

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Skin changes	23%	Eye problems	27%
Hyperthyroidism	16%	Swallowing problems	25%
Neck pain	11%	Voice change	23%
		Neck pain	20%
		Hyperthyroidism	19%
		Skin changes	17%

Confidential: For Review Only

DISCUSSION

This study has shown that the majority of patients who underwent definitive treatment for Graves' disease had at least some understanding of the alternative treatment option available to them (80%), felt involved in making the decision making process (84%) and were satisfied with their treatment (85%). Other studies in Graves' disease have shown similar levels of satisfaction with radioiodine and surgery (4,10). A randomised controlled trial from Sweden comparing medical treatment, radio-iodine and surgery in Graves' disease showed that 90% of patients from each of the three treatment groups were satisfied with treatment (9).

A key finding in this study was that involvement in decision-making was found to be positively associated with satisfaction with treatment. This has been demonstrated in other situations and should provide further encouragement to clinicians to ensure patient involvement in making treatment decisions (11-13).

The discussion with the doctor was considered to be the most important aid in decision-making. Information leaflets were found to be useful in the decision making process in 55% and the internet in 37% of patients. Given the use of internet by a significant proportion of patients, doctors may consider recommending reliable sources of web based information. Discussion with friends and family was helpful in 53%; this was more marked in those undergoing surgery. The reasons for this are unclear.

Before radioiodine treatment, the concerns related to avoiding contacts with others, remaining hyperthyroid and the radioactive nature of the treatment. Remaining hyperthyroid after radio-iodine ablation was cited as a concern by 25% of patients undergoing surgery and 59% of patients undergoing radio-iodine ablation. However, the chance of remaining hyperthyroid is reported to be less than 20% (14,15). Although, patients should be informed of this risk routinely, it should be reiterated that persistent

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3 hyperthyroidism is uncommon and that a further dose can effectively address the
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5 problem.
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7 The idea of having surgery under general anaesthesia was the common reason for not
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9 undergoing surgery. This was also a concern for 63% of patients before surgery. In
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11 patients undergoing surgery, the main concerns were physical complications of scarring,
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13 swallowing problems, voice change and neck pain (see table 3). 23% of our patients
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15 felt that voice change was a concern after surgery. This is similar to those in another
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17 study, where 29% patients believed that they had experienced voice change (10).
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20 Despite this, a greater number of patients were satisfied or very satisfied with surgery
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22 (91%) than radioiodine (80%). The higher satisfaction rates in the surgical group could
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24 be attributed to several reasons. Patients with more severe disease (with associated large
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26 goitre or thyroid eye disease) tend to be referred more often to surgery (16). A greater
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28 relative improvement in well-being following treatment may therefore have contributed
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30 to higher scores. Patients in the surgical group are also more likely to have further
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32 consultations (with the surgical and anaesthetic teams in addition to endocrinologists)
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34 before treatment, arguably resulting in a greater opportunity to be involved in decision
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36 making and treatment planning. It is also likely that the surgery and radio-iodine cohorts
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38 are likely to differ in demographic features as radio-iodine is more likely to be used in
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40 elderly patients with comorbidity while surgery in the young patients with children.
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42 This has not been explored as the relevant data on demographics were not collected,
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44 given the nature of the study (service evaluation).
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49 The perception of being hypothyroid was the most common on-going concern raised in
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51 both groups. This was greater in the radio-iodine group (60%) compared to in the
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53 surgery group (43%). This may be reflected in the difference between the predictability
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55 in developing hypothyroidism. Following surgery, the development of hypothyroidism
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3 is immediate and patients are started on thyroxine the next day. In contrast, after
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5 radioiodine the development of hypothyroidism may take months and is not easily
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7 predicted. Patients may be concerned about when they will develop hypothyroidism
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9 and how it will affect them.
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11 This study has identified the common concerns in patients undergoing definitive
12
13 treatment for Graves' disease. Clinicians should aim to provide detailed information
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15 and offer to discuss these issues when considering treatment options with patients.
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17 Addressing concerns in a shared decision making process and empowering patients will
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19 improve patient satisfaction with whichever treatment they undergo. Our results also
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21 highlight that there are a wide range of reasons for choosing RIA or surgery. Some are
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23 concerns specific to only a few patients; but in these patients, they may be major factors
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25 in the decision making process. In addition to common concerns, clinicians treating
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27 Graves' disease should also develop strategies for exploring the less common concerns.
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30 The study has several limitations. The surgery group included patients from nearby
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32 hospitals who were referred by local endocrinologists at these hospitals specifically for
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34 thyroid surgery to be done by the endocrine surgeons in this centre. This may explain
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36 the relatively large number of patients undergoing surgery for Graves' disease at this
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38 centre. As the survey was conducted around 9-39 months after definitive treatment, the
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40 responses are subject to recall bias. This would be particularly relevant to some
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42 questions such as information on the provision of information and concerns before
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44 treatment. In a study of patients undergoing thyroid surgery, 69% of patients
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46 remembered only one or two of the possible complications mentioned prior to surgery
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48 and 12% could not remember any at hospital discharge.(17) The study did not use any
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50 validated questionnaires or scores to assess concerns such as voice, hypothyroidism or
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52 scar related issues as the main objective of the study was to assess overall satisfaction
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3 following definitive treatment and to gain an understanding into prior and ongoing
4 concerns from a patient's perspective. Another limitation of the study is that an
5 objective assessment of reported concerns was not done as it was outside the scope of
6
7 the project.
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11 12 13 14 **CONCLUSION**

15
16 The majority of patients are satisfied with their definitive treatment of Graves' disease,
17 but those that underwent surgery are more satisfied than those who had RIA. Reasons
18 for this may be multifactorial. The reasons underlying choice of definitive treatment
19 and concerns regarding treatment are several and vary from one patient to another.
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21 Understanding this will improve the provision of appropriate information for patients
22 and will help them in the decision making process. Patient involvement in the decision
23 making is important and this involvement will increase their satisfaction with treatments
24 received.
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