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1 Abstract

*Purpose:* To gain an understanding of how the IR community is taking up renal artery denervation for resistant hypertension by approaching a quantification of several parameters including demographics of IRs performing RDN, the volume of procedures performed, the devices used, usual referral pathways and factors limiting and driving the growth of the procedure.

*Methods:* An anonymous online survey was distributed to all full CIRSE Members, asking distinct sets of questions to sub-samples of renal artery denervation performers and non-performers. Data was collected for 5 weeks and then analysed statistically.

*Results:* From a total of 466 responses recorded, a final sample of 422 statistically usable responses was formed (return rate of 10.5%, considerably higher than previous CIRSE member surveys). This sample was split into sub-samples of 121 performers and 301 non-performers. Collected data indicates that although still a low volume procedure, the population of RDN performers amongst CIRSE Members is optimistic about the procedure’s future and willing to participate in clinical research to better understand what is still and unproven prospect.
2 Purpose and Aims of the Survey

2.1 CIRSE and Renal Denervation

Great hopes have been placed in renal denervation (RDN) as a new therapy for resistant hypertension since the publication of encouraging early clinical results. Procedure numbers have reportedly grown at a considerable pace since then, spurred on by media attention and a fervent reaction from the medical device industry, and are set to continue to grow with renal denervation now being explored for indications going beyond resistant hypertension.

In light of the promising early results, the rapid uptake of the procedure and increasing member demand for information, the CIRSE leadership established a Renal Denervation Task Force in 2012 to guide the Society’s activities in this field (See principal investigators p.2 for task force membership). In order to define the best possible support strategy for CIRSE Members, the Task Force decided it was essential to gain an understanding of how IRs are embracing the nascent procedure and what Members really need and expect from CIRSE. This survey was designed to address this requirement and was issued in collaboration with the CIRSE Office’s Research and Analytics Department.

2.2 Purpose and Aims

The purpose of this survey is to explore the current performance of renal artery denervation amongst CIRSE Members through social scientific research methods. It is designed to yield data that will permit basic inferences about the current performance of the procedure amongst interventional radiologists practicing in Europe. Furthermore, it is conceived to offer an evidence-base for the development of a support strategy by the CIRSE RDN Task Force. Ultimately, this exploratory enquiry is intended by the researchers to help answer two core questions:

- How many IRs currently perform renal artery denervation in Europe?
- What are the characteristics of this population?

To achieve this, IRs’ behaviour, perception and professional circumstances connected to the performance (and non-performance) of renal denervation were researched. The following variables were defined as significant endpoints:

<table>
<thead>
<tr>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>renal denervation performance</td>
</tr>
<tr>
<td>procedure volumes</td>
</tr>
<tr>
<td>device usage</td>
</tr>
<tr>
<td>referral pathways</td>
</tr>
<tr>
<td>future predictions</td>
</tr>
<tr>
<td>other indications for performing renal denervation</td>
</tr>
<tr>
<td>drivers and limiters to providing an RDN service</td>
</tr>
<tr>
<td>demographics</td>
</tr>
</tbody>
</table>
3 Methods

The principle that guided the design of this enquiry’s methodology was to maximise the evaluative usefulness of results, whilst keeping research design as straightforward and respondent-friendly as reasonably possible. The researchers agreed a quantitative enquiry with statistical analysis to be the method that would best meet these requirements and provide the most comprehensive overview of RDN performance amongst CIRSE Members.

The methods used are not intended to provide deep psychological insights into attitudes or behaviour of IRs and are subject to some limitations (See 5 Limitations). Rather, the methods aim to produce a continent-spanning, quantitative profile of IRs’ current RDN performance.

3.1 Data Collection

An anonymous electronic survey was designed and distributed to the CIRSE Members database via e-mail on Monday 25th March 2013. One reminder e-mail was sent out 14 days later on Monday 8th April 2013. Data collection was ceased a further 21 days following the reminder, concluding a total of 35 days (five full weeks) of online data collection.

3.2 Sampling

In order to maximise responses, the survey invitation and reminder were sent to the entire sample frame of full CIRSE Members. A certain degree of randomisation is inherent in this technique whilst some bias must be expected (See 5 Limitations).

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1 Respondents had the opportunity to leave personal details at the end of the survey if they wanted to be contactable for a future renal denervation registry. These details were isolated from the remaining data points and collated in separate lists to preserve the anonymity of responses to other items.
3.3 Questionnaire Design

The online questionnaire was designed to focus on the core variables (See 2.2 Purpose and Aims of the Survey) in addition to being brief and simple to answer. Following the initial demographic items, respondents were split into sub-samples of (renal denervation) Performers and Non-performers by the only mandatory question of the survey: Do you currently perform renal artery denervation? (at least one treatment in the last 12 months).

Depending on the answer to this question, respondents took one of two routes through the questionnaire, containing different sets of questions. Performers (answer yes) answered a maximum of 13 items split into five sections: info & demographics, procedure volumes, procedure detail, your medical centre, future predictions. Non-performers (answer no) answered a total of five items in two sections: info & demographics, predictions. Some pop-up logic was built into the e-questionnaire to minimise unnecessary questioning and optimise ease-of-use.

Question types included single and multiple choice items, a total sum item in which respondents had to indicate the relative percentages of referrals adding to a total of 100% (What is the usual referral pathway for the renal artery denervations you perform? Please indicate the percentages that apply.), open response fields and a contact form (See 8.2 Questionnaire for a full transcript).

The survey was originally composed in English and translated by native speakers of German, French, Spanish and Italian. Medical vocabulary (i.e. renal artery denervation, referral pathway) was translated and confirmed as valid by interventional radiologists that are native speakers of the respective languages.

The survey was programmed electronically and hosted online, using the surveygizmo tool (See screenshot, p.6). Double responses were blocked with browser cookies.

3.4 Missing Data

44 cases that only answered the questionnaire partially (less than 20% of questions answered) or were identified as duplicates were deemed unreliable and deleted. Otherwise missing responses were found to be either random or most likely due to respondent fatigue.

3.5 Analysis

The analysis and presentation of the data gathered in this study rely heavily on descriptive statistics. Frequency tables illustrated in pie or bar charts make up the bulk of analysis.

Some inferential bivariate analysis was used to support the discussion of findings. Standard chi-squared significance tests were performed as well as a 2x2 contingency table matrix with attached chi-squared and Fischer’s Exact tests of significance.

Open responses were analysed qualitatively and coded into significant categories.
4 Results

The invitation email was successfully sent out to 4027 individuals (full CIRSE Members working in Europe), 1301 of which opened the mail\(^2\). A total of 466 responses were recorded. 44 responses could not be taken into statistical consideration (See 3.4 Missing Data), resulting in a final sample of 422 responses.

This amounts to a return rate of **10.5%**, considerably higher than previous CIRSE member surveys. This is attributed to two main facts: the heightened interest in renal denervation at the time of questioning and the CIRSE Research & Analytics department offering the questionnaire in multiple languages for the first time:

<table>
<thead>
<tr>
<th>Language</th>
<th>Unique persons who followed survey link(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>187</td>
</tr>
<tr>
<td>French</td>
<td>26</td>
</tr>
<tr>
<td>German</td>
<td>104</td>
</tr>
<tr>
<td>Italian</td>
<td>39</td>
</tr>
<tr>
<td>Spanish</td>
<td>20</td>
</tr>
</tbody>
</table>

4.1 The Sample Obtained

Age distribution was close to expectations, reflecting the demographics measured in previous CIRSE Member surveys (See Fig. 1). In terms of influence on device purchasing decisions, **84.4%** of respondents answered positively, indicating that CIRSE Members generally have a say when it comes to the acquisition of technology (See Fig. 2).

The key result from the initial item set was, however, that **28.7%** of respondents indicated that they performed renal artery denervation for resistant hypertension at the time of questioning. This amounted to sub-samples of **121 performers** and **301 non-performers** (See Fig. 3).

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\(^2\) Email blast statistics were retrieved once the survey was closed.

\(^3\) There is a discrepancy between the sum of survey links clicked in the invitation email (376) and actual responses received (466). This is attributed to certain software settings that do not allow for email feedback, or individuals navigating to the survey through some other channel than the official invitation link (e.g. passed on by a colleague, copied link and pasted into browser).
Fig. 1: Age distribution (n=422)

- 30 years or below: 3.6%
- 31 - 45 years: 40.5%
- 46 - 60 years: 47.4%
- over 60 years: 8.5%

Fig. 2: Do you have an influence on the medical device purchasing decisions made by your institution? (n=422)

- yes: 84.4%
- no: 15.6%
4.2 Performers

A total of 121 IRs, representing 28.7% of the drawn sample, indicated that they performed renal denervation for resistant hypertension at the time of questioning. This sub-sample is designated *performers* in the context of this study. Performers were questioned about their annual activity, device usage\(^4\), usual referral pathways, future predictions, performing RDN for other indications, membership in a multidisciplinary team, participation in a RDN registry and how they would like to see CIRSE support interventional radiologists performing renal denervation. The following presents the collected responses.

4.2.1 Annual Activity

A large majority of CIRSE Members (90.8%) perform between 1 and 20 procedures per year, 45.8% of respondents only treating up to five patients (*See Fig. 4*). A significant minority perform between 21 and 50 procedures (7.5%) and two individuals indicating that they perform between 51 and 100 procedures (1.7%).

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\(^4\) Only devices that held a valid CE mark at time of questioning were included in the questionnaire.
4.2.2 Device Usage

The results concerning which devices IRs use show a clear market dominance of Medtronic, with 77.7% of respondents indicating that they currently use the Symplicity device. However, notable alternatives to Medtronic have emerged in the form of St Jude (EnligHTN, 14% market share) and Covidien (One Shot, 5.8% market share). ReCor Medical (Paradise) and Boston Scientific (Vessix V2) were both relatively late to gain CE marking for their devices and are still measured at below 1% market share (See Fig. 5).

Market share results are practically mirrored in the distribution of responses to the item: Which of the following devices have you used in the past (at least 1 procedure)? (See Fig. 6). It was unusual for doctors to have tried more than one device, with only 15.7% indicating they had done so.

Interestingly, market shares amongst those IRs who had tried at least two systems differed markedly to the market shares observed in the total performer sample (See Fig. 7). Results showed Medtronic and St Jude head to head at roughly a third of market share each (36.8%) with Covidien a strong third at 15.8%. This relationship was statistically significant (p < 0.001), although based on a small sample (n=19).
Fig. 5: Which device do you currently use for renal artery denervation? (n=121)

- Medtronic (Symplicity): 77.7%
- St Jude (EnligHTN): 14%
- Covidien (One Shot): 5.8%
- ReCor Medical (Paradise): 0.8%
- BSCI (Vessix): 0.8%
- Other: 0%
- Missing: 0.8%

Fig. 6: Which of the following devices have you used in the past (at least 1 procedure)? (n=121)

(respondents were asked to indicate all that apply)

- Symplicity (Medtronic): 102
- Paradise (ReCor Medical): 1
- One Shot (Covidien): 11
- EnligHTN (St Jude): 22
- V2 Vessix (BSCI): 2
- Other: 1
When considering the distribution of referrals to IR between different specialties it is useful to first look at how many sources IRs tend to receive their cases from (See Fig. 8). 42.1% of IRs receive all their referrals from one, exclusive source. This distribution drops linearly, with a third (33.6%) of IRs receiving referrals from two sources and 15% from three sources. 5.8% of respondents indicated they receive referrals from more than three sources.

**4.2.3 Referral Pathways**
The results for the total sum item asking IRs to indicate their referral sources and respective share of referrals show a high variance. In the aggregate, two disciplines can be identified as clear leaders though: 66.3% of questioned IRs receive referrals from nephrologists and 54.9% from hypertension specialists. Together the two disciplines account for almost three quarters (73.7%) of all cases referred to IRs.

Cardiologists only refer to 41.6% of questioned IRs but tend to do so in significant volumes; when they do refer to radiology, cardiologists are on average found to provide over half the renal denervation cases (54.4%). Cardiologists are also the most likely to be exclusive referrers to IR, 29.8% of those that receive referrals from cardiology indicating that they are the exclusive referrers.

Direct referrals, although received by a considerable proportion of IRs (17.7%), tend to be few and far apart, only making up 3.7% of the total referral volume.
4.2.4 Predictions

There seems to be little doubt in CIRSE Members’ minds that renal denervation is here to stay (See Fig. 10). Only 5.8% of respondents were unsure about renal denervation’s future development, a notable measurement for such a young (and still unproven) procedure. A large majority, three quarters of IRs (75.9%), believe that the number of renal denervation cases will increase while 11.7% believe case numbers will remain approximately the same. Two individuals (0.8%) suggest that renal denervation procedures will decrease in future.
4.2.5 Other Indications

8 respondents (6.6%) indicated that they performed renal artery denervation for other indications than resistant hypertension (See Fig. 11). Cardiac failure (n=4) and renal insufficiency (n=3) were the most common indications, sleep apnoea and polycystic ovarian syndrome each receiving one mention (See Fig. 12).
4.2.6 The Multidisciplinary Team

73.6% of RDN performers work in a medical centre that has a multidisciplinary team in place for the discussion and selection of resistant hypertension cases (See Fig. 13). A large majority of 95.5% of respondents that work in such an environment are also a part of the multidisciplinary team (See Fig. 14).

Fig. 13: Does your medical centre have a multidisciplinary team (MDT) for discussion and case selection? (n=121)

- yes: 73.6%
- no: 19.8%
- missing: 6.6%

Fig. 14: Are you a member of this multidisciplinary team (MDT)? (n=88)

- yes: 95.5%
- no: 4.5%
4.2.7 RDN Research

The survey asked performers whether they would be willing to participate in a renal denervation registry if CIRSE were to set one up (See Fig. 15). 68.6% answered positively, and over 80 contacts were gathered by the survey for future reference.

A high missing number was recorded for this item (18.2%), possibly reflecting respondents already enrolled in a registry or generally unsure of the situation. In hindsight, including an “I am unsure/already enrolled in a registry” option, may have improved the validity of this item.

4.2.8 Support

The open text field responses collected by the item asking respondents to suggest how IRs performing RDN could best be supported were translated and underwent content analysis. 63 relevant suggestions were collected from 47 respondents and coded into five categories according to the types of support mentioned (See Fig. 16).

The two most common suggestions were those for scientific support in the form of educational content or guidelines (33.3% of responses) and for increased data collection (23.8% of responses). Support through gaining
financing/reimbursement, the strengthening of interdisciplinary ties and the strengthening of IR vs. competing specialties were also noted as notable requests although were less frequent, all around the 15% mark.

As must be expected for open response items there was a high number of missing answers. This limits the representativeness of results and makes judging relative importance of support areas difficult. All five areas of support measured below are accepted as meaningful and significant suggestions by CIRSE Members in the scope of this enquiry.

Fig. 16: In what way would you like to see CIRSE support interventional radiologists that are performing renal denervation? (n=47, 72 missing) (open response)

<table>
<thead>
<tr>
<th>Support requests</th>
<th>count</th>
<th>% of requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational support/guidelines</td>
<td>21</td>
<td>33.3%</td>
</tr>
<tr>
<td>Data collection</td>
<td>15</td>
<td>23.8%</td>
</tr>
<tr>
<td>Financial/Reimbursement support</td>
<td>10</td>
<td>15.9%</td>
</tr>
<tr>
<td>Strengthening of interdisciplinary ties</td>
<td>9</td>
<td>14.3%</td>
</tr>
<tr>
<td>Strengthening of IR vs. competing specialties</td>
<td>8</td>
<td>12.7%</td>
</tr>
</tbody>
</table>

4.3 Non-Performers

301 respondents (71.3% of the total sample) indicated that they did not perform renal artery denervation for resistant hypertension and are designated non-performers in the following. Non-performers were asked what prevented them from performing renal artery denervation and if they thought that this may change in future.
4.3.1 Limiters and Predictions

In terms of reasons for IRs not performing renal denervation, three answers initially emerged as limiting factors (See Fig. 17). The lack of demand for the procedure at the respective medical centre was the most common response, indicated by 32.9% of respondents. This was followed closely by the lack of funding for the procedure (29.5%) and the procedure being provided by another medical department (23.9%).

76 other responses, equating to a quarter of questioned non-performers (25.2%), had some reason for not performing RDN not included in the answer options. This does suggest that the answer options may not have been exhaustive and limit the expressiveness of this item.

In line with RDN performers’ high expectancy that procedure volumes will increase (See 4.2.4 Predictions), a majority of non-performers believe that they will perform renal artery denervation in future (See Fig. 18). This belief is, however, not shared universally. Cross-tabulation reveals that those non-performers confronted with another department providing renal denervation do not believe that their situation will change (See Fig. 19).

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**Fig. 17: Why do you not perform renal artery denervation? (n=301)**

*(respondents were asked to indicate all that apply)*
Fig. 18: Do you think this might change in future? (n=301)

- Yes, I think I will perform renal artery denervation in future: 62.8%
- No, I don’t think this will change: 36.9%
- missing: 0.3%

Fig. 19: Limiting factors cross tabulation with future predictions (n=300, 1 missing)

<table>
<thead>
<tr>
<th>Limiter</th>
<th>Yes, I think I will perform RDN in future</th>
<th>No, I don’t think this will change</th>
<th>Significance Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>%</td>
<td>#</td>
</tr>
<tr>
<td>No demand for the procedure</td>
<td>65</td>
<td>65.7%</td>
<td>34</td>
</tr>
<tr>
<td>No funding/reimbursement for the procedure</td>
<td>68</td>
<td>76.5%</td>
<td>21</td>
</tr>
<tr>
<td>RDN provided by another department</td>
<td>19</td>
<td>26.4%</td>
<td>53</td>
</tr>
<tr>
<td>Other limiting factors</td>
<td>58</td>
<td>77.3%</td>
<td>17</td>
</tr>
</tbody>
</table>
5 Limitations

Several limitations to this study’s methodology must be mentioned to put the discussion of results into context, in particular in terms of the representativeness of results for the wider IR community.

A certain degree of selection bias is inherent in the sampling methodology. Not every IR in Europe can be expected to be a Member of CIRSE, although the coverage is assumed to be high, and thus included in the database that was used as sample frame. Since the entire sample frame was contacted electronically, an overrepresentation of those CIRSE Members that check their electronic correspondence diligently is also likely.

Furthermore, CIRSE Members that had strong feelings about or a strong interest in renal denervation must be expected to have responded in greater numbers. Thus, it is probable that the proportion of RDN performers (See 4.1 The Sample Obtained), who can be expected to have strong feelings, is inflated and may not be representative of all interventional radiologists in Europe.

A pervasive limitation to this survey must be expected from the status of renal denervation as a nascent therapy. It has only really found its way into radiological departments over the past 12 to 18 months and a number of aspects are still in flux, such as standards of practice, devices used as well as habitual behaviour and thinking. Thus, it is important to understand the presented data as a snapshot in time of the circumstances and behaviour connected to this procedure. This is particularly relevant when considering the market share measurements (See 4.2.2 Device Usage) as well as the future predictions for renal denervation (See. 4.2.4 Predictions & 4.3.1 Limiters and Predictions). A large randomised controlled trial including a sham treatment arm is currently underway (HTN-3) in the United States. This study is expected to be decisive for the future of renal denervation for resistant hypertension as it could offer high-level proof of the concept or expose factors that have obscured the truth about the procedure’s effects so far.

Since this survey was designed to give a workable overview of the shared situation in Europe, it cannot take into consideration the relative heterogeneity of health provision across the continent and the starkly differing professional circumstances under which interventional radiologists work. Despite the researchers’ efforts to keep the questionnaire as comparable as possible, some bias must be conceded.

6 Discussion

Despite some inevitable limitations to the research methodology used, it is the opinion of the researchers that the results provide a valid and workable quantitative exploration of the behaviour and attitudes of interventional radiologists that perform renal denervation in Europe.

The results strongly suggest that a notable percentage of CIRSE Members currently offer or will in future offer a renal denervation service. Although a very robust measurement (422 responses, 10.5% of CIRSE Members), one must be
careful not to overrate the, probably inflated, proportion of CIRSE Members performing RDN of 28.7% that this survey may suggest (See 5 Limitations).

The results unquestionably offer well-sized samples of 121 CIRSE Members that perform the procedure and 301 that do not. The following offers a brief discussion of CIRSE Members’ behaviour, attitudes and circumstances observed in the course of this survey. The subsamples of performers and non-performers are treated separately as well as the measurements relating to device usage which are discussed in the economic terms of renal denervation device market shares.

Performers

To the knowledge of the researchers, this is the first enquiry to specifically research RDN performance amongst IRs. This explorative quality, while rendering the interpretation of results somewhat speculative due to the lack of comparable data, is suggested to be one of the most valuable attributes of the profile of IR renal denervation performers offered below.

Contrary to what the current media hype may imply, the results of this survey indicate that renal denervation is still a low volume procedure (See 4.2.1 Annual Activity). 90% of CIRSE Members estimate their activity at a maximum of 20 cases per year. This is in line with the researchers’ expectations for such a new therapy and reflects the limited reimbursement available. Although a small fraction of respondents indicate procedure volumes of up to 50 per year, it must be concluded that the medical and financial potential of renal artery denervation is still to be fully tapped. This will constitute a collaborative process, greatly dependent on clinical results which CIRSE Members seem well suited to decisively participate in, in terms of prevalence of RDN performers and procedure volumes.

In terms of which referral pathways are usual for RDN performers the survey results show a high variance, indicating that no one “typical” distribution of referrals can be identified at the European level. Nephrologists and hypertension specialists are by far the most common and heavy referrers to IR, accounting for 3 out of 4 cases. Cardiologists refer considerable case volumes in a more concentrated form and direct referrals are surprisingly prevalent yet only provide few cases. These findings, in combination with the observations that a majority of CIRSE Members receive referrals from at least two sources and participate in multidisciplinary teams for case selection, lay evidence to the interdisciplinary nature of renal denervation practice (See all 4.2.3 Referral Pathways). The fostering of good interdisciplinary cooperation, which was also explicitly requested in 9 open responses, must be expected to be of central importance to performers of renal denervation and certainly a meaningful goal for the Society to pursue.

This sample suggests a distinct optimism about the future of the procedure amongst renal denervation performers. A large majority of those who perform RDN believe that procedure numbers will increase in future and would be willing to participate in a registry, if CIRSE were to initiate one. This optimistic, pro-active stance is also supported by 15 open

5 HTN-3 trial, (See 5 Limitations)
response requests for support in data collection. In summary, these results suggest that IRs see a future in renal denervation and are willing to take part in shaping this future by participating in clinical research.

**Market Share**

While it was a single system (Medtronic’s Symplicity) that produced the impressive clinical results that sparked the rapid growth two years ago, the number of CE-marked renal denervation systems is expected to go into double figures by the end of 2013.

The data gathered by this survey suggests strongly that Medtronic’s first-mover advantage has translated into a dominant market leadership amongst interventional radiologists. However, significant competition is emerging in the form of St Jude’s EnligHTN and Covidien’s One Shot systems (See all 4.2.2 Device Usage). As clinical evidence for newer devices is published and reimbursement is broadened Medtronic’s market position will be increasingly challenged. Newer devices that potentially employ more developed technology pose a threat to Medtronic’s position.

The volatility of the current market situation is exacerbated if one takes into account the optimistic growth prognosis of renal denervation performers and non-performers alike (especially since the concept is not yet conclusively proven). If the market really does grow according to IRs’ expectations there will be a considerable future demand for renal denervation technology and a greater choice of devices for doctors to choose from. Thus, while Medtronic holds a clear market leadership position at the moment, this is expected to diminish as competition grows and device usage will most likely diversify amongst IRs.

**Non-Performers**

In terms of what limits the performance of renal denervation by CIRSE Members, the lack of demand, the lack of funding and competition from other medical specialties all emerged as equally notable factors. The equal distribution and high count of other answers do, however, limit the expressiveness of the data supporting this observation.

Despite the apparently numerous factors limiting the provision of a RDN service, a majority of non-performers think that their situation will change and are distinctly expectant of performing renal denervation in future. Cross-referencing the limiting factors with the IRs’ predictions of the future indicates that this optimism is not shared by all non-performers. IRs hindered by lack of demand, lack of funding and other factors believe these will subside as limiting forces in future. IRs who stated that competition by another discipline is a hurdle do not share this optimism and a majority believe that this will not change in future, revealing this to be the most significant barrier to IRs offering a renal denervation service. It is suggested that competition among medical specialties is also a potential threat experienced by

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6 Medtronic was the first manufacturer to present favourable clinical results and launch its renal denervation technology (April 2010), over a year before any competition entered the market.
those that already perform renal artery denervation, with eight open responses requesting some form of strengthening of IR against other specialties.

7 Conclusion

It can be concluded that this survey accomplished its exploratory mission and successfully identified and quantitatively profiled a distinct group of CIRSE Members that perform renal artery denervation.

The data gathered on the population of renal denervation performers amongst CIRSE Members, although not perfectly representative of the wider IR population does allow for basic inferences to be drawn. Results suggest that IRs perform volumes of RDN that are expectable for a procedure at this stage in its development and are well embedded in the multidisciplinary treatment pathway, routinely cooperating with nephrologists, hypertension specialists and cardiologists. IRs are markedly optimistic about the growth of RDN procedure volumes and show a high willingness to participate in clinical research.

Data gathered on the device usage amongst IRs confirms Medtronic’s current market dominance although St Jude and Covidien both appear to be emerging as significant competition. IRs, RDN performers as well as non-performers, predict procedure numbers to increase in future and market shares can be expected to be subject to change.

This enquiry also offers useful indications of possible drivers and limiters to RDN performance amongst IRs. Open responses from CIRSE Members identify 5 key areas in which improved Societal support could prove beneficial, educational support/guideline publication and data collection being the 2 most important. Competition from other catheter-skilled medical specialties seems the most significant limiting factor to the performance of RDN by interventional radiologists.

Ultimately, this survey suggests that, observed at a European level, IRs are in a good position to co-determine the future of renal artery denervation. The optimism about the future of RDN and willingness to partake in clinical research indicate an enthusiastic, pro-active population. IRs are willing to expand the use of renal denervation for resistant hypertension with the necessary clinical evidence-base and could certainly profit from targeted support measures at the European level.

It is the researchers’ opinion that CIRSE’s activities in the field of renal denervation so far\(^7\) have laid a solid foundation, which the Renal Denervation Task Force, with the help of the information provided by this study, will be able to build on in future.

\(^7\) A societal position paper with nephrological commentary was composed, cooperation with the European Society of Hypertension was initiated and RDN courses and hands-on workshops were reviewed and extended.
8 Appendices

8.1 Open Field Responses

Responses entered in a language other than English are presented in translated form below. Comments in English language are replicated exactly as they were entered by respondents.

<table>
<thead>
<tr>
<th>Count</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initiate data collection - registry and multi centred clinical trials</td>
</tr>
<tr>
<td>1</td>
<td>Institutional Support, Clinical Guides, Contribution to the leadership of the technique(s)</td>
</tr>
<tr>
<td>1</td>
<td>by providing updated research results about the ongoing trials.</td>
</tr>
<tr>
<td>1</td>
<td>Cardiologists will try to monopolize this procedure. CIRSE with the National Societies of Interventional Radiology must find a way to protect our work.</td>
</tr>
<tr>
<td>1</td>
<td>course</td>
</tr>
<tr>
<td>1</td>
<td>Dedicated free workshop in CIRSE, ECR or regionally. Cardiologists have an edge on securing initial funding. Generator lease for regional centres.</td>
</tr>
<tr>
<td>1</td>
<td>Dedicated sessions during the annual congress, a detailed database over centers performing procedures and dedicated small courses.</td>
</tr>
<tr>
<td>1</td>
<td>Education</td>
</tr>
<tr>
<td>1</td>
<td>Education, exchange of materials. Support in getting this procedure reimbursed by the health insurance fund.</td>
</tr>
<tr>
<td>1</td>
<td>Enable ir to lead on rdn rather than allow cardiologist to continue controlling and performing the procedure</td>
</tr>
<tr>
<td>1</td>
<td>Facilitating assistance/aid/help for your courses and congresses</td>
</tr>
<tr>
<td>1</td>
<td>Facilitating access to courses and to the publications of the other members</td>
</tr>
<tr>
<td>1</td>
<td>Funding from CCGs/PCTs</td>
</tr>
<tr>
<td>1</td>
<td>Get involved in joint statements for clinical indications (ie. with British society of hypertension and cardiology bodies) to ensure ir role in treatment and to be more proactive in uk commissioning process.</td>
</tr>
<tr>
<td>1</td>
<td>There are two problems: high price of the devices and the increasing interest of the hemodynamists to realize this type of procedures. I believe that something should be done about this, in order to avoid duplicities at the moment of carrying out these and other procedures.</td>
</tr>
<tr>
<td>1</td>
<td>I would like to be included in clinical studies, registries or another development programs regarding the topic.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1</td>
<td>we must secure national reimbursement, contribute to clear and mandatory studies, which would allow us to make use of this technique</td>
</tr>
<tr>
<td>1</td>
<td>Informative material, Information about reimbursement, clinical study updates</td>
</tr>
<tr>
<td>1</td>
<td>Information about pathophysiology  Information about Indications  Information about state of evidence  How to build a RDN team in your hospital  The least we need is: how to do it (too simple)</td>
</tr>
<tr>
<td>1</td>
<td>keep radiologists involved! We perform these procedures together with cardiologist, who are about to take over decisions...</td>
</tr>
<tr>
<td>1</td>
<td>Lobby for greater IR representation for renal denervation</td>
</tr>
<tr>
<td>1</td>
<td>Through informative talks, pamphlets, where it is emphasized that the person responsible for the technology must be a professional interventional radiologist or a cardiologist with experience in vascular renal procedures</td>
</tr>
<tr>
<td>1</td>
<td>meetings multidisciplinari</td>
</tr>
<tr>
<td>1</td>
<td>More clinical data</td>
</tr>
<tr>
<td>1</td>
<td>More clinical support to help influence the purchasers of this procedure.</td>
</tr>
<tr>
<td>1</td>
<td>More co-ordination between centres, registry, political representation to involve IR compared to cardiology as cardiology appear to be main people involved by decision makers at the moment at least in UK.</td>
</tr>
<tr>
<td>1</td>
<td>Patient information  Position paper</td>
</tr>
<tr>
<td>1</td>
<td>practice guidelines for proper patient selection  up-date on new devices</td>
</tr>
<tr>
<td>1</td>
<td>Printed materials</td>
</tr>
<tr>
<td>1</td>
<td>Promote studies in this field. More scientific data are needed to assess it's application.</td>
</tr>
<tr>
<td>1</td>
<td>Promoting clinical and financial benefits to commissioning bodies.</td>
</tr>
<tr>
<td>1</td>
<td>Promoting our service with nephrology/cardiac and vascular groups</td>
</tr>
<tr>
<td>1</td>
<td>Promotion of good practice, scientific data, registry as proposed.</td>
</tr>
<tr>
<td>1</td>
<td>Provide an overview of the competencies required to undertake the procedure. Supervise a registry for long term assessment.</td>
</tr>
<tr>
<td>1</td>
<td>Providing guidelines for safe practice, selection criteria, pre-procedural imaging and need for an interventional radiologist!</td>
</tr>
<tr>
<td>1</td>
<td>Providing information to give to referrers and commissioners to support development of a service.</td>
</tr>
<tr>
<td></td>
<td>Description</td>
</tr>
<tr>
<td>---</td>
<td>-------------</td>
</tr>
<tr>
<td>1</td>
<td>Raising awareness among health policy makers and governments of the long term cost efficiency of the procedure.</td>
</tr>
<tr>
<td>1</td>
<td>Implement courses</td>
</tr>
<tr>
<td>1</td>
<td>Implementing formation courses. Promoting interdisciplinary workgroups and reducing the protagonism of the cardiologists.</td>
</tr>
<tr>
<td>1</td>
<td>To increase publicity work - as done by cardiologists - they are everywhere in press &amp; tv :)</td>
</tr>
<tr>
<td>1</td>
<td>To organize workshops, courses and good register</td>
</tr>
<tr>
<td>1</td>
<td>To provide proctoring for at least ten procedures to understand the spectrum of eventualities of renal denervation</td>
</tr>
<tr>
<td>1</td>
<td>Trials</td>
</tr>
<tr>
<td>1</td>
<td>It would be useful to develop a European multicenter trial</td>
</tr>
<tr>
<td>1</td>
<td>Unfortunately we had to stop renal denervation, as our clinicians do not have patients eligible for the procedure....</td>
</tr>
<tr>
<td>1</td>
<td>We are already partners in the EncorED network group.</td>
</tr>
<tr>
<td>1</td>
<td>We started the procedure with the nephrologist to avoid a take-over of the method by the cardiologists. It should be pointed out that the renal artery is not the heart!</td>
</tr>
</tbody>
</table>
8.2 Questionnaire

The questionnaire was designed and distributed electronically, a text transcript is provided below.

CIRSE Member Survey: Renal Denervation in Europe

Intro and Demographics

What is your age?*
( ) 30 years or below
( ) 31 - 45 years
( ) 46 - 60 years
( ) over 60 years

Do you have an influence on the medical device purchasing decisions made by your institution?*
( ) yes
( ) no

Do you currently perform renal artery denervation? (at least 1 treatment in the last 12 months)*
( ) yes
( ) no

Annual Activity and Future Predictions

How many renal artery denervation procedures do you perform per year?
( ) 1 - 5
( ) 6 - 20
( ) 21 - 50
( ) 51 - 100
( ) over 100
**Which of the following devices have you used in the past (at least 1 procedure)?**
*please note that this information is envisaged for internal use only, this survey is not part of a commercial agreement and responses are not respondent-traceable*

(please indicate all that apply)
- [ ] Symplicity (Medtronic)
- [ ] Paradise (ReCor Medical)
- [ ] One Shot (Covidien)
- [ ] EnligHTN (St Jude)
- [ ] V2 (Vessix)
- [ ] other, please specify

**Which device do you currently use for renal artery denervation?**
*please note that this information is envisaged for internal use only, this survey is not part of a commercial agreement and responses are not respondent-traceable*

( ) Symplicity (Medtronic)
( ) Paradise (ReCor Medical)
( ) One Shot (Covidien)
( ) EnligHTN (St Jude)
( ) V2 (Vessix)
( ) other, please specify: ________________________________________________

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**Annual Activity and Future Predictions**

**What is the usual referral pathway for the renal artery denervations you perform?**
*please indicate the percentages that apply*

- [ ] Hypertension specialist
- [ ] Nephrology
- [ ] Cardiology
- [ ] direct referral
- [ ] other

**Do you expect the number of procedures to change in future?**
( ) I think it will increase (+)
Do you perform renal artery denervation for indications other than resistant hypertension?
( ) yes
( ) no

What are the other indications you perform renal artery denervation for?
please select all that apply
[ ] sleep apnoea
[ ] cardiac failure
[ ] renal insufficiency
[ ] polycystic ovarian syndrome
[ ] other, please specify

Does your medical center have a multidisciplinary team (MDT) for discussion and case selection purposes?
( ) yes
( ) no

Are you a member of this multidisciplinary team (MDT)?
( ) yes
( ) no

Registry and Follow-Up

Would you/your center be interested in participating in a renal artery denervation registry if CIRSE decided to set one up?
( ) yes
( ) no
Please enter your details so we can contact you:
Title: ____________________________________________________
First Name: _________________________________________________
Last Name: _________________________________________________
Medical Center: _________________________________________________
Active Email Address: __________________________________________

In what way would you like to see CIRSE support interventional radiologists that are performing renal denervation?
____________________________________________
____________________________________________
____________________________________________
____________________________________________

Future Predictions

Why do you not perform renal artery denervation?
please select all that apply
[ ] I generally don't perform vascular interventions
[ ] There is no demand for the procedure at my center
[ ] This procedure is provided by another department in my center
[ ] There is no funding/reimbursement for the procedure
[ ] Other, please specify
[ ] I am retired

Do you think this might change in the future?
( ) Yes, I think I will perform renal artery denervation in the future
( ) No, I don't think this will change
Thank you!