

# Episode 2 Transcript: Why we need to be talking about hair regrowth, not just hair retention?

### Richard Paxman 00:01

Hi, my name is Richard Paxman. Welcome to the changing the face of cancer podcast. In this episode, I will be talking to two guests on regrowth and scalp cooling. I will firstly be talking to Dr. Jyoti Bajpai, an oncologist in Mumbai, who prioritizes providing precision symptom care for her patients - despite the huge quantity of patients she sees daily. Dr. Bajpai's interest in side effect management led her to carrying out a randomised controlled trial on scalp cooling. We discuss not only her discoveries on regrowth, but also the importance of treatment sequencing to reflect each individual patient's definition of success. I just want to say Dr. Bajpai absolute pleasure to have you as a guest today on our new podcast. It's wonderful, you've made the time. Really interested in hearing all about the study and about regrowth and really about scalp cooling in general practice in India. First of all, like to hear a little bit more about yourself. So Dr. Bajpai, why don't you tell us a little bit about what got you into oncology? What was the driver to become a doctor and then perhaps specialize in oncology?

### Dr Jyoti Bajpai 01:11

So great question, I would say Richard, and I always love to interact with people and to know about them. And if I can pitch in and solve if they're having any kind of difficulty, so that was right, from my school time, you know, if somebody is having some kind of problem, it could be anything personal, professional study related, then people generally they used to talk to me, and I love that counselling sessions very early in my childhood. So that grows on and I, you know, started developing a tremendous interest and similar fashion that if I can really heal, you know, patients, also a few of the, you know, very closely associated members in my family, they were having diabetes and cardiac issues. So in my early time period, my childhood, I had an experience to go to hospitals, and see what difference a doctor can make into the patient's life. So that was my inspiration. And so I love challenges in my life. And oncology, I found it very challenging. So I thought perhaps this is the thing for me, and I moved from there.

### Richard Paxman 02:15

Fantastic. And I love that from a young age, you've been interested in helping people and you've been that go to for people to seek counsel. So obviously a very passionate and caring person, which I've of course experienced from day one of meeting you. How long have you been at Tata Memorial Hospital, then how many years have you been there? And I won't give away your age.

### Dr Jyoti Bajpai 02:33

Right. So I would say that my training involved my DM in medical oncology from All India Institute of Medical Sciences, which I did in 2009, from Delhi, which is the capital of India. And immediately after that, I joined Tata Memorial Hospital,



and I'm still there. I love this place. Also, in my training, you know, I have twice, you know, an experience to working abroad. So I was having got observership from Johns Hopkins, and immuno oncology and melanoma from Memorial Sloan Kettering. So those were, for the brief period, I could experience the other part of the world and care difference.

### Richard Paxman 03:13

Fantastic. And it's an interesting point you raise, how would you sort of describe the differences between, let's say, healthcare at Tata Memorial Hospital compared to that of Memorial Sloan Kettering? What are the biggest or major differences that just to set the scene in terms of the level of care, of course, is high, but what are the biggest differences.

### Dr Jyoti Bajpai 03:33

The major differences are numbers, numbers of the patient we need to treat and the numbers of caregivers. So that proportion varies, that we are having less time for counselling our patients because we get a large number of patients, each one of us. So there is a difference. I loved those long counselling sessions in Sloan Kettering or John Hopkins, otherwise, care wise, I would say both the centres are par excellence. And they are doing a great job in the respect about the world to help patients,

### Richard Paxman 04:04

I think from experience in terms of being to both, both offering absolutely amazing care, but it's that volume, isn't it? I've you know, walking through the doors of Tata Memorial Hospital and seeing the patients in the waiting room just doesn't compare to many places in the world, to be honest. So yeah, how many patients do you treat roughly? How many patients do you see a day, you personally?

### Dr Jyoti Bajpai 04:23

We see between 60 to 100 patients at times more in general side, even they cross 120, 130, 150 at times, each day, so a consultant and one or two residents together they see this number of patients each day. So there we are, and we learn to deliver messages fast in the limited span that is also a part of our training process, I would say.

## Richard Paxman 04:47

So remind me and it was some years ago what got you interested in scalp cooling? Where did you first hear about scalp cooling?



## Dr Jyoti Bajpai 04:53

Right? I feel the quantity of life is very important, but as well as the quality of life. So if somebody would ask me that, You are having a 50 or 60 years of good quality years or you are having 100 years with not that good quality, I perhaps would choose the first option. So quality is very, very important. So I'm a medical oncologist here I treat predominantly breast cancer. And my other major area is rare cancer, which I'm very passionate, equally passionate. So rare cancers involves my in my practice sarcomas, all sorts of bone and soft tissue, sarcomas and melanoma, which is rare in our part of the world. And also I'm deeply interested in pregnancy associated cancers, so rare cancer and breast cancer. So these are my area of interest. And among these, also, I'm very, very inclined towards young patients care. Because I feel there are very different kind of challenges at this age. And when a young person gets affected, the whole family gets affected in a very different fashion. So a young woman back, you know, from a very strong young woman career oriented, working lot at home for that professional front, managing kids, managing relations, and suddenly diagnosed with as a breast cancer patient. It's a tremendous transition, which many people find it very difficult to cope with. And the children's care get affected, their career becomes, you know, compromised, their partner's career, everything. So those are the major issues. And within that, because of virtue of being young, they're, they're more aware, cosmetically, they're about their appearance about the quality. So those are the real challenges, which we cannot really ignore them. Then when I used to talk with these woman, in Tata, we see, you know, patients from private side, semi-private, general, all the categories. So there's a spectrum and majority of our patient belongs to the general category, we are in we are a very low cost care, and they are not able to afford very fancy treatment, very newer therapies also. But I what I've seen in practice that from both these worlds, like whether this is a general category patient who are not very educated or not very aware of many things, or be it a private category, patient who might be very educated, and few of them are really can afford everything also. And some of the patient even tell me that I can afford everything under the sun, perhaps including the sun. So there is a wide spectrum, you know, but both of these different patients, they will get affected by losing breast or losing hairs. I haven't come across any patient who say that, who really say that I don't care, especially if they're a young woman. So at times, they try to pretend because they feel that the doctor will feel good. But if you really go close, and they're definitely affected inside. And many of these women even said to me that because there's such a stigma associated with cancer, many times they don't want to disclose this, that they got cancer, because it is still in many of the parts of India and other low middle income countries, it is a kind of taboo to get diagnosed with cancer, they don't want to tell. But even if they don't tell this kind of losing hairs on chemotherapy tell every time everybody that they are facing this kind of challenge. So they find it very catastrophic. And at times previously, I used to think that perhaps it is affecting more to those educated, aware women who were career oriented, but I found it is equally affecting both in different manner. So I was very badly affected when I saw a woman who was actually abandoned because of her hair loss, who was from a remote village and the family it is not acceptable that about a women in their family. So it was such a, you know, major effect on that woman's life. Some woman even said to me that they found it more difficult to cope with losing hairs than even to lose a breast, because they still have options to cover that aspect. So I was really, really wanting to help them in any which manner. And I came across that there are several kinds of options available right from the penguin caps way back, to these kinds of systems, which are, you know, Western world, pretty commonly used and with good results. So I was very keen to start it in our country. And fortunately you also reach to me. So I would say it was kind of a joint endeavor, I would say and we could do that.

Richard Paxman 09:26



Fantastic. So I remember many years ago, in fact, I can't remember how many years ago, you and I wrtr sat with our partner in India and a number of your colleagues around the board table at Tata Memorial Hospital. And I know I mentioned this to you before, but I think I walked out the room thinking that's a frosty audience. I'm not quite sure if they're ready for scalp cooling yet or have a full belief in what it might offer their patients. How do you think the attitudes have changed now since we carried out this or perhaps with some of your colleagues who may just not have been as confident in the treatment as perhaps you were.

### Dr Jyoti Bajpai 10:05

Many people were skeptical about that, whether doing scalp cooling can increase the scalp metastasis rate that was the major fear and even the caregivers as well as in the many patients. So that was the major thing with the data emerging, and especially if the meta-analysis by Rugo et al., all those things they have shown successively that this fear is actually not really true. So when I share this data with my colleagues, then they were convinced and also people were very much concerned about whether, because the temperature of the scalp will go down significantly, how will be the tolerance? So people felt that because our part of the world is different than the cold countries that people are not really so much accustomed to get so much cold. So it will be all they were worried that perhaps they will be having a lot of side effects. So then we decided that when we will do this trial, we will do very stringently, of course, an initial 10 patients, we will note everything. And if things are really developing major side effects, then we will reconsider how the trial will progress. So fortunately, they tolerated really well. And in my study entire randomized trial, nobody was having any grade three side effects, they were having grade one side effects, more than half of the population had grade one side effects, so some kind of headache, or some kind of coldness, but that was pretty tolerable. And so 50% plus patients 57 around, they were having grade one side effects, 12% Grade Two, but none grade three, four. So when we stringently did that initial ten patients and shown this to all other colleagues, they were pretty sure that this is, you know, this is tolerating well. An even aside, very funny incidents like in summer, because Indian summer is also very difficult. So some patient even told me that it is quite soothing. So those kinds of things will happen. So also basically everybody was concerned about the patient safety, and this thing, so gradually, when we could show that the tolerance is good, and efficacy was also, it has shown good results. So then people are convinced that yeah, this is a good treatment, which can add on to their care.

### Richard Paxman 12:18

So would you would you like to tell me a little bit about the trial design, then just so the audience knows, you know, inspiration for the study design? What did we look at primary endpoints, that sort of thing. And then perhaps we'll talk about the results and what that looked like.

### Dr Jyoti Bajpai 12:32

Sure. So essentially, it was a randomized controlled trial. And we decided to go with two to one randomization so that we can, we can offer scalp cooling to more patients in comparison to the control group, and can do this trial at appropriate speed. Also, we do this randomization and we do counselling. At times I had this difficulty that many patients were very



interested, they wanted only to choose scalp cooling. So when we have given them option to do you will go into either of the arm, they refuse to come. So then, you know, after appropriate counselling, we randomize them and depending on the arm, as if they are coming into scalp cooling arm, our dedicated nurse, they fixed the size of the cap. So there are three cap sizes available. So and later on, you have provided us with the ultra-small cap also in our demand, because what we found while we are doing trial that the head size of the Indian patient will be different than the people from other geographic areas. So if the cap fit is very, very important, I want to give this message very loud and clear that the cap fit is a very important component and if the cap is not snugly fit at wherever people lose hairs from that part. So we even see the patchy loss of hairs at a part where the cap fit was not appropriate. So that's why I'm very keen and I had a discussion also with you that there has to be customized gaps for irregular heads, because not everybody is having that smooth round head. So whenever we are not able to snugly fit that part, we were having a chance to lose hairs. So our team have a trial team. They were very dedicated people and they try to fix the cap very snugly. So that is most important. Mechanical. Yeah.

### Richard Paxman 14:16

Interesting that you had that learning curve. And I think we've seen that in a number of studies just where the nursing team become more proficient at fitting the cap or the patient perhaps if it's their responsibility. Yes, we see better results. Yeah, absolutely. I promise to get that personalized cooling cap to you in the future.

### Dr Jyoti Bajpai 14:31

Yeah, that would be that would really make a difference because you know, it makes a difference. I've seen that the people who were very round headed were and we could fit the cap very appropriately. They had a very good result while those who are not there and especially the frontal part, that cap fit there are some gaps at times and where we lose hairs and that part and which is more visible also. So ultimately you need to camouflage that less than 50% loss of hair. But if it is just at the top area, then it's visible. So those parts are very important. And the real world scenario, actually a word of caution, because if the cap fit is not proper, we will not be able to mimic those trial results. So that's why the dedicated nursing staff were well trained, and it's time consuming also we need to really take time to fit in. So if in a very haste, somebody will do that, then we will not get so good results. That's what we have to be careful.

### Richard Paxman 15:29

And I think you bring a valid point up there, moving from clinical trial to real, real world settings. And that education piece is incredibly important for our nursing teams, and also the patient and we were trying to move forward putting more emphasis on the patient to take that ownership that the cap fits well. And in some markets, that's easier than others, but it is absolutely critical. On the study, we looked at regrowth, which you know, when you actually presented this data to there was very limited regrowth data available, what drove you to want to look at regrowth and tell me a bit about the results what did you see



## Dr Jyoti Bajpai 16:04

Right, so, very interesting question and important as well. So, basically, you know, the two things are important one, how long patient can postpone the hair loss, that is one thing. So chemo induced alopecia, can we prevent it, can we decrease it, can we postpone it all these are important. Similarly, I found it is important that how early they can regain their hair. So our primary endpoint was chemo induced alopecia. And other secondary endpoint I introduced was the hair regrowth rate because I found it is equally important that how widely the patient, even if they are losing, is this device is helping them to regrow their hair faster so that they can go back to normal life fast. So what I found that as is seen in the literature on other studies as well that there are some chemotherapy which are having more potential to have loss like anthracyclines. So the results with anthracyclines were comparatively less yielding than with the taxanes, so with the taxanes 70% above patient could preserve their heads at the primary endpoint. So, primary endpoint was at the four cycles, as was in other studies also. So generally in the clinics, we see that after first cycle only they had a good amount of hair is gone and till second cycle, almost everyone is having a complete alopecia in anthracycline-based chemotherapies. In taxanes it is little delayed, but still they have significant alopecia till the end of four cycles. So we fixed that primary endpoint at the end of four cycles. And we see depending on the sequence of chemotherapy, we are using taxanes first or whether we use anthracycline first, this primary endpoint success was much better in taxanes first patients. And that is corroborated with other studies as well. So if you're using taxanes 70% of the time, there are chances that after four cycles you will be having preservation of your hair still less than 50% fall. So that also we have to be very carefully making understand everybody that we'd used WHO criteria, so if patient can preserve 50% of the hairs that is a success. At times the expectations are very different. Some people felt that they shouldn't be any single hair loss, which is not practical. So we have to counsel them very well about that part also, because some say there are different kinds of patients, some patients are into that kind of jobs, that kind of work that they will, they're very, very aware and conscious about their appearance and every then if they imagine that with this, they will not lose a bit of their hair then perhaps your life would be difficult at the end of when you're achieving these endpoints. So counsel well and primary endpoint we see that there are very good results for taxanes, for anthracyclines they were somewhere around 30%. Plus, if you are using anthracycline first and then at the primary endpoint, the patients are not able to preserve the 50% of hairs. But still, when they taxane arm is started, it was very interesting to see that they started regrowing, they started regrowing during the taxane phase. So that those hair buds even the patient who became completely bald, the hair buds appearing fast, and by the end of 12 weeks while we're completing, a good amount of hair regrowth is seen. And at our secondary endpoint time period, six weeks after the completion of chemotherapy, which is usually the general recovery time also after the chemotherapy, when patient wants to go back to their normal life, their jobs, etc. By then a significant amount of patient could regrow their hair to grade zero or one. So we have a difference of 89% versus 12%. 89% in the test on the patient who were used to scalp cooling versus 12% in the control arm. So there's a significant difference and at 12 weeks period, another time point which we take for like three months follow up, then almost 100% of patients had regrowth of hair if they use the scalp cooling, so 12% at 12 weeks had growth while they are not using a scalp device. At six weeks, they are almost nil. So that was a huge difference we could see. So we can counsel the patient that even if you are using anthracycline first and you will lose your hairs early, but then your regrowth will be very fast. So these both endpoints, I feel are equally important.

Richard Paxman 20:18



Yeah, absolutely. And I think regrowth is becoming more and more important in our discussions and our counselling with patients. What was the patient feedback like then when you explained that regrowth could be better or actually when they really visibly saw regrowth was better, was this something positive? Did they really feel the benefits?

## Dr Jyoti Bajpai 20:37

Yes, so they really felt the benefit, they were very happy because you know, majority of them they have, they want to go back to their normal life, some they want to go back to their work life, some go back to their social lives. So this is really important. One patient categorically remember she was a woman who wanted to fix her daughter's wedding etc. And that was a big ceremony for her, she wanted to look as normal as possible. So she could regrow her hairs. And that was a very positive move for her. Also some of the patients who could join back to their jobs with a confidence in them because they could regrow their hair. So I think that definitely makes a differences, also, we did a quality of life analysis. So the quality of life analysis has shown that with respect to one factor, which is the losing hairs, it was significantly different between the two arms. The other aspect of quality of life were not different. But we need to understand that when patients on treatment and chemotherapy, toxicity etc, that was also a very important determinant for other aspects of quality of life. This one factor, which is actually the essence of this particular kind of study that losing hairs were significantly different. And also, I learned from this study of ours that we don't really have proper quality of life indicators, or many tools to capture alopecia very adequately, and we need to develop - that is another message which I learned from these patients and my study.

### Richard Paxman 22:04

Yeah, more work needs to be done in that area to capture that impact of quality of life. And hopefully, I believe we will get there in the future with the work that's been done internationally. But let's hope that happens soon. So we can get some really quantitative data behind it. Because I think qualitatively we believe that there is a positive impact. We were confident in that. Just having that better measure that a more appropriate measure. Is there any standout patients who were part of the trial that you know it really made a big difference to. I know, you touched on the person who managed to attend their child's wedding is there anyone else that sort of stands out to you that gives you sort of a 'this really made an impact'?

### Dr. Jyoti Bajpai 22:44

So you know, one of the patients again, I categorically remember her she was a very young, very pretty beautiful lady and with a very long and thick hairs. She was so much worried about her potential health because she was so much attached with the hairs, and she was crying while we were planning a treatment that she doesn't want to lose, she doesn't want to lose. When we counsel her about scalp cooling she was very adamant that I will only go into scalp cooling because there is a chance to preserve I will not opt for that. But then we had to explain that no, you have to be ready but that is the only option because we are doing it under trial setting only. So then she after you know a long session of counselling, she agreed. And then she was praying hard that she should come in to you know, randomized into scalp cooling, and fortunately she was in the scalp cooling arm. And then she was receiving anthracycline first, so we were just hoping because



the success of initial anthracyclines for weeks were not as good as initial for taxanes. So we were really worried because she was so much concerned. But fortunately for her, she loses really merely 5% or 7% of her hair's until and she could preserve those long big thick hairs. But I mean, we were extremely happy.

#### Richard Paxman 24:03

So scalp cooling in India then, so what does scalp cooling in India look like as of today, has it grown since the trial, is there more interest based on the work that you've done?

### Dr. Jyoti Bajpai 24:14

So certainly it has picked up well and a lot of people got interested especially because they've seen that it is very well tolerated, the efficacy is also good and before people were very concerned. And now majority the people understood that the scalp metastases is not a major concern with the data emerging. And discussed it with a lot of people, a lot of units, lot of scientists very interested, they have connected to me several times to understand smaller, finer aspects I would say and when they're convinced they're using it. So definitely it has offered this trial there are many many people in centres which got interested in this device.

### Richard Paxman 24:53

And with Tata having such a wonderful name in in India in terms of the hospital and the clinical trials you run it really provides that validity, which is wonderful. And we we cannot thank you enough for your support and your continued support. So what do you think the future of scalp cooling might look like in India? Do you think this is going to be something that eventually gets to standard of care? Or have we got a long way to go? What's your thoughts?

### Dr. Jyoti Bajpai 25:18

Ultimately, it should require an appropriate place. That's what I feel our current challenges are, the turnover of the patients because we have so many numbers. And our day cares are really flooded. So in high turnover centres like ours, the problem is that our day cares get a lot many patients to foster over. So when we do scalp cooling, our time of treatment increases, because we have to do a pre cooling time and the post cooling time. So almost two hours, we have to increase the timing. So there comes the challenge and also the space occupancy. So once we will be able to build more day cares more centres, I think, then perhaps we will be able to offer this to every patient. And also one thing is reimbursement. So at present, it is not reimbursable. So that's also a bit of a challenge. I think it should be it's an important thing. And once that part is also taken care of the acceptability would be much more, that's what I would say,



Richard Paxman 26:17

Dr. Bajapi, what does changing the face of cancer mean to you personally?

Dr Jyoti Bajpai 26:22

So I would say that precision care, one size cannot fit all. That very thought and that very action, the person sitting across to you will be given you're having several options are limited is getting widened each day, each minute, I would say. Now, we also joke that if you are boarding a flight to reach a conference, while you are getting out, there are several other things which are in the development. So that's a very fascinating thing in cancer, the development is fantastic. And also we are trying to increase the quantity of life also we are concentrating on quality of life. So both aspects becoming important and precision care for both aspects, I would say was the things which were considered fancy is reality today. So that is where we are. And it's no longer that stigma. It is one of the disease which we can handle. Many cancers we have really conquered, and in several we are learning to tame the beast. And I'm sure in my lifetime, there will be several more which we will say that we have conquered.

### Richard Paxman 27:28

Yeah, I hope so too, I think yeah, huge movements in this space. And we cannot thank you enough for all that you do for your patients and also contributions to future developments in cancer as well. So thank you for today. And thank you for all that you're doing. You've been a wonderful guest. And we look forward to hopefully seeing each other in the future and not having to live by zoom or by web conferencing. I can't wait to get back out to India and see you there.

Dr Jyoti Bajpai 27:57

Absolutely. So thank you very much.

### Richard Paxman 28:03

Now I'll be chatting with Professor Toi, a breast oncologist from the University of Kyoto in Japan. We discussed his involvement in the HOPE study, a multicenter controlled clinical trial on scalp cooling, which was revolutionary in the investigation into the role of hair regrowth as well as hair retention. Welcome, Mark, it's an absolute pleasure to have you on our podcast today. Really looking forward to talking to you a little bit more, learning a bit about you, about your experience in oncology. But I think more importantly, about scalp cooling, hopefully and some of the data that you've collected in Japan over the years. I'm trying to think when we first met actually, it was in Glasgow at one of the European breast cancer conferences, wasn't it? Yeah. Time flies, Time really flies. So just to start with Mark, what got you into oncology? What made you start looking to become a physician? And I nearly said many years ago, but



### Prof. Masakazu Toi 29:05

That is a big question, actually. And the important thing to me was that my father died of lung cancer when I was 18 years old, just quickly after I'd entered into the medical school, he was 49 years old. At the time, cancer treatment was very primitive. We didn't have any good drug treatment for lung cancer particularly. So that's when I decided to study about oncology in medical school. The last year of medical school, I met a great mentor at Hiroshima University. There I decided to go to the Sashko department of cancer treatment. That's the beginning and the professor actually suggested me to study about the breast cancer, so I decided to go to breast cancer treatment or research works.

#### Richard Paxman 30:05

I'm sorry to hear that you lost your father at such a young age, as you know, I know, too well, at that age, it has a has a real impact on you, doesn't it? But you've obviously used that impact and done so much good over the years and been involved in many, many clinical trials and helped many patients over the years. So thank you for all that you do. So in terms of scalp cooling, then what got you interested in scalp cooling? I know of course, we met in Glasgow. So is that the first time you'd heard about scalp cooling and hair loss prevention?

### Prof. Masakazu Toi 30:41

I think I heard multiple times from the different persons about scalp cooling. I was actually concerned about something. But the Glasgow meeting was very important to me. You and your colleagues suggested multiple things, including the hair stem cells. That's actually the beginning to me.

### Richard Paxman 31:06

Fantastic. And I think actually, you may have met at that time, some of my colleagues from the University of Huddersfield and they were, yeah, were starting to really understand a little bit more about the mechanisms behind scalp cooling and, and more about hair loss, which was exciting. So when we met, we talked about study design, and all those years ago, and it took some time, of course, to get through the PMDA and the regulatory hurdles to get to where we are today. Could you tell me a little bit about the HOPE study, who was involved in it, which centres, but also a little bit about the trial design as well, I think the audience would love that to hear that about it.

#### Prof. Masakazu Toi 31:45

Actually Dr. Kinoshita at the time at the National Cancer Centre Hospital, he was exceedingly interested in this project. And he initiated as a pilot study, in my understanding, he first tried the scalp cooling, with your machine actually, in Japanese



patients. So after that we discuss a lot about what is the best way to get a good result in Japanese, the patient society, then we asked PMDA and we decide we discuss a lot of things to be in a good clinical trial to get good results. Technically, we have got a lot of things, the scalp shape, somehow different within the Caucasians and Japanese or Asians. And they have the how it should be tightly fit. So I remember very well still another discussion we've got.

Richard Paxman 32:43

So you used independent reviewers for looking at one of the endpoints, which of course was assessing hair loss. So like in many of our studies, the primary endpoint was losing less than 50% of your hair, not requiring a wig or head cover.

Prof. Masakazu Toi 33:00

Yeah, that's right.

Richard Paxman 33:01

And my understanding is that the result was chosen by two independent reviewers. So if both were negative results, that we would choose the negative, the negative result. Tell me a little bit about the differences in the assessment from both reviewers? Were they were they always comparable? Were they were they different each time?

Prof. Masakazu Toi 33:27

I think they were mostly comparable. But for some cases, the different opinion, then they discuss each other's and decide.

Richard Paxman 33:36

And do you think that's related to some subjectivity around measurements of hair loss?

Prof. Masakazu Toi 33:41

I think it was very subjective. In my view, they were very strict about assessment and also judgement. And totally independently done so that there were no bias. Yeah, very objective.

Richard Paxman 33:59



What interested me, I guess, was the fact that if we chose the negative result, each time we got a success of around, you know, just under 30%. And I think you had five photos, was that correct?

Prof. Masakazu Toi 34:12

Yeah, that's right.

Richard Paxman 34:13

If you look, it showed that if you chose the positive option, it would be at efficacy around 60%. So quite a range. So the HOPE Study was the first study to look at regrowth as an endpoint. What made you add regrowth as an endpoint, or hair recovery, shall we say?

Prof. Masakazu Toi 34:31

Yeah, at the time of the completion of chemotherapy we assessed and then three months later, we assessed again, about our picture, quite amazing, the more than 85% of the patients got a recovery in terms of the hair volume of over 50%, about. So that's just amazing to me, it's a big difference compared with the control patients.

Richard Paxman 35:04

I recall seeing some of the pictures from the study as well. And it really is very clear that that hair recovery is impressive.

Prof. Masakazu Toi 35:12

I want to say more than expected I guess.

Richard Paxman 35:15

And more than I expected actually, we talked about it anecdotally for years, but never really captured the data. So we were delighted with those results. What did your patients think about the regrowth, was that was that something they found beneficial?

Prof. Masakazu Toi 35:26



No patients were absolutely happy after, but usually patients do not know about the natural cause, physicians do know about it, patients do not know.

Richard Paxman 35:37

That's an interesting perspective. So as a physician, of course, you know, if they're not having scalp cooling, let's say, you know, when they're going to lose their hair roughly. And then you know, roughly when it's going to start growing back to a reasonable level, whereas the patients currently know they will lose their hair most likely. So a commonly known sort of outcome of chemotherapy, whether you've had had cancer or not, but I guess they don't understand that regrowth. I guess we need to educate patients to understand not only what regrowth or improve regrowth is but to understand what regrowth might look like if they don't have scalp cooling.

Prof. Masakazu Toi 36:21

Yeah, for example, 10 months after the chemotherapy completion, we used to say like this, the hair would grow back 80%. But nowadays, with a scalp cooling, the explanation would be different from previously, the recovery time would be shorter than previously expected time.

Richard Paxman 36:49

So if you were talking to a patient of yours, a breast cancer patient having a taxane based therapy, they were interested in scalp cooling. Would you talk about the overall efficacy of scalp cooling, and would you talk about regrowth also?

Prof. Masakazu Toi 37:04

Yeah the patients are interested in when their hair is back. So we need to say something about when it should be. So that maybe it's now becoming half the recovery time. That's my feeling.

Richard Paxman 37:20

I think as an organization, we also need to do more to talk about regrowth and, and hopefully watch this space as we build that more into our educational pieces going forward. After your wonderful HOPE study with your colleagues, there's been further publications.

Prof. Masakazu Toi 37:37



That's really important.

Richard Paxman 37:38

In terms of management of expectations, then, how would you normally talk to your patient about scalp cooling? Is there anything you say from a management of expectations perspective? Do you sort of, how would you normally talk to a patient?

Prof. Masakazu Toi 37:55

I firstly, I explain about the mechanism, why the cooling down is important. And the secondary how this system is used in many countries, obviously, United Kingdom - this is a good example to explain. And also we need to explain about our own clinical trial data, us and other studies.

Richard Paxman 38:21

So we here at Paxman talk about changing the face of cancer. So that means different things to different people. So what do you think changing the face of cancer means, what are we trying to achieve?

Prof. Masakazu Toi 38:33

I think the treatment outcome, the prognosis, getting better and better. Maybe .5% annually, for example. This is quite good way now. On the other hand, the adverse events, prevention, protection, it's not like these, we need to do more things to improve the quality of life. Before the treatment, out of term prognosis then quality of life now getting you know, something like this and should be equal in the near future.

Richard Paxman 39:12

Agree that sort of holistic approach to that patient's treatment?

Prof. Masakazu Toi 39:15

Yeah, that's right. Yes. Yeah.



### Richard Paxman 39:18

Well, Mark, I can't thank you enough for today really do appreciate it. It's wonderful to hear from both Professor Toi and Dr. Bajapi on this really important subject of regrowth. Both are real trailblazers in this area of research and have really put it to the forefront of scalp cooling. Thank you for listening to this episode of Changing the Face of Cancer. Everything we have discussed today can be found in the shownotes. In our next episode, I'll be joined by Dr. Conleth Murphy, and clinical nurse manager Sue Glavin from Bon Secour Hospital in Cork, to discuss patient advocacy within Ireland for side effect management, the psychosocial impact of hair loss as a result of chemotherapy, and the differing perceptions of scalp cooling success among patients and their health care providers