



Registo  
Português  
de Artroplastias  
Portuguese  
Arthroplasty  
Register

Until this month ....  
More than **10 000** hip arthroplasties registered



Issue n.º5

## RPA's mission is to improve the quality of arthroplasties in Portugal

### Dr. Alexandre Diniz

Director of the Quality  
in Health Department Of  
the Portuguese Directorate  
General Of Health

“WE NEED TO KNOW WHICH IMPLANTS ARE USED, AND HOW THEY INFLUENCE THE QUALITY OF LIFE OF THE PATIENTS”

Launched in October 2010, the National Observatory for Arthroplasties (ONA), which runs under the auspices of the Portuguese Directorate General Of Health, serves as the interface between the data collected by SIGIC (system used to manage the wait list of patients due to have surgeries) with the data collected by RPA (Portuguese Arthroplasty Register). In an interview, Alexandre Diniz says that the major objectives of this Observatory are “the characterization of the concrete clinical practice, the analysis of the degree of safety of the arthroplasty surgery, and the collecting of data which will allow to establish clinical practice guidelines for the health professionals”.



Did you know that...

... Curry Cabral Hospital, in Lisbon, was the fourth to achieve the 1.000 register mark?

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## EDITORIAL

TACKLING WAIT LISTS  
AND ARTHROPLASTIES

Tackling the surgical wait lists is a major project which has contributed a great deal to facilitate the access to healthcare, and to solve some delays which are absolutely inhumane, but also some glitches of the system, such as the false enrolment, or the pending surgeries which were managed in such a deregulated and permissive manner, which lead to shady manoeuvres and power games.

Nevertheless, this fight, when applied to arthroplasty surgery, has revealed some perverse effects. It is known that an arthroplasty is a very rewarding surgical procedure, because it immediately leads to more function of the joint and improves the quality of life of the patient. But on the other hand it is also a very condescending surgery, i.e., it allows for some technical variability, without the immediate result being affected in any way. Now, the medium and long term objectives may not be exactly as expected. We can see this pattern around the world.

Taking as an indicator of quality of health management, the availability of an arthroplasty surgery measured in time the patient had to wait for the surgery, was revealed to be a mistake. Putting pressure to meet deadlines for this kind of surgery does not favour the quality, at all.

That is what some countries of the OECD already noted, namely the United Kingdom and Sweden, where arthroplasties are no longer in the list of surgical procedures included in the wait lists. This happens when they realized that they could be compromising the benchmark of survival at 10 years higher than 90%.

The tackling of wait lists is a noble and rightful political flag, but one has to be prudent and establish the right criteria of the pathologies to include in this list. Surgical procedures as condescending as arthroplasties are, allow for a wide variety of techniques, but, between the technical variability admissible and the pure and simple error, there is a very thin line still to be defined. When you unintentionally cross that border, will result, sooner or later, in the need for revision surgery, which is a very expensive procedure, which completely demolishes the excellent cost/effectiveness balance we have in primary surgeries, when the primary surgery is successful.

The absence of quality as a great cost, which you cannot easily attribute to the decision makers, because, when it is verified, the political cycle or the tenure of the hospital administrator will be over. But this cost has to be paid and its price will be, invariably, supported by the final payer, the public, in other words, by all of us.

Chairman, RPA,  
**J. Costa Ribeiro**

PUB

## THOUGHT OF THE MONTH

## THE TEN-YEAR MYTH

→ The idea that an arthroplasty has a life-span of ten years (after which it will have to be reviewed) is one of the myths more solidly installed amongst the patients. But it is absurd.

It's like the refrigerator one has at home had to be changed after the two-year warranty expires. That is not the case!

An arthroplasty has to last more than ten years. This has always been the case, but now, mainly because the orthopaedic implants, in what concerns the risk of these implants, have been reclassified from class II b to class III. This reclassification implies a higher degree of rigor in the tests and clinical trials needed in order for the company to obtain a trading license.

If an implant last less than ten year, than it is an exception, not the rule. And, in those cases, we need to evaluate what went wrong: the implant, the surgical technique or the patient. And when the surgeon figures that out, the mistake will not be made again. **J. Costa Ribeiro**

REGISTRATION RATE IN  
THE AZORES

We already have the official numbers of the arthroplasties performed in the Azores islands, in the first year of RPA – from June 2009 until May 2010. Even though more people register, it is still a small percentage:

→ The Santo Espirito Hospital, in Angra do Heroísmo, registered all the arthroplasties they performed (100%);

→ The Divino Espirito Santo Hospital, in Ponta Delgada, registered only 1/3 of the arthroplasties performed (33%);

→ The Horta Hospital did not register any of the arthroplasties they performed, even though they have already registered 37 of the arthroplasties they performed on this second year of RPA activity;

→ The Bom Jesus Clinic (private entity) in Ponta Delgada, registered some of the private arthroplasties they performed (not within the scope of the National Health Service).

## EDITORS



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## Dr. Alexandre Diniz

Director of the Quality in Health  
Department of the Portuguese General  
Directorate of Health

“We can develop corrective measures and guidelines for Good Clinical Practices (with the data from the National Observatory for Arthroplasties)”

If there is something in common between the National Observatory for Arthroplasties and the Portuguese Arthroplasty Register, it is its mission: improve the quality of the arthroplasties performed in Portugal. The Director of Quality in Health Department of the Portuguese General Directorate of Health (DGS), points out the first steps of this journey.



### → What added value, in terms of quality, will the National Observatory for Arthroplasties bring to the panorama of the articular implants in Portugal?

While the Portuguese Arthroplasty Register is limited to the members of the Portuguese Society of Orthopaedics and Traumatology (SPOT), and its focus is almost exclusively clinical, the National Observatory for Arthroplasties (ONA) is to observe, on a national level, this panorama, as a whole. Thus, it is a macro-analysis. Every year, there are thousands of surgeries regarding articular implants, and we need to know which implants are used, how long do they last, and what is their impact in the quality of life of the patients, and we also need to know the costs this area represents of the National Health System.

From the analysis of the data collected (and if we come to the conclusion that there is a great variability in the application of articular implants for identical situations), we can develop corrective measures and guidelines for Good Clinical Practices, and we will obviously do that in conjunction with SPOT. Hence, the interest of the Ministry of Health is to analyze the national panorama, and not individual cases.

### → Nevertheless, the activity of the Observatory may lead to individual repercussions. So, what are the specific measures that may come from the action of ONA?

The major actions that will be taken by ONA, will be the characterization of the concrete clinical performance, in global terms; the analysis of the degree of safety of the arthroplasties for the patients; and the collection of information in order to draw up general technical guidelines, geared towards the health professionals.

### → When can we expect the first visible effects of ONA?

In Health, nothing changes all of a sudden. We will obtain information on a short-term (which will be collected by the Integrated System for the Management of Patients in Surgery Wait List (SIGIC) and by SPOT), but that, once analyzed, may lead to the make up of guidelines, with the aim of the improvement of the arthroplasties performed in Portugal, and that is not a task that can be accomplished on a short-term basis. In order to understand the evolution of the panorama of arthroplasties, we will draw up, annually, a report (with quantitative and qualitative analysis), which will be presented

to the health authorities. And we will start to work, on the field, as soon as we are able to articulate the data series of SIGIC and the data series of RPA.

### → Does ONA already have an activity plan outlined?

This plan is the process of being outlined. But, surely, there will be some points included, that I can already advance, such as, the steps we have to undergo with the National Data Protection Commission, in order to have a better performance of the Observatory. On the other hand, we want to know, we need to integrate the systems related to ONA such as the SIGIC and the RPA. Another priority is the elaboration of guidelines for the professionals who work in this area, to raise awareness for the existence and running of ONA, as well as to appeal to the surgeons to register the arthroplasties they perform, both in public and also in private institutions. Finally, in this phase, the Observatory will have to nominate representatives in the 5 regional health administrations (ARS'), and these representatives will help the Observatory to be more dynamic and will help enhance its performance. ¶

## The importance of the health observatories

The informative newsletter nr. 46/DSPCS of October 13 2006, of the General Directorate of Health, which defines some guidelines about the activity of the centers for health observation, highlights the pertinence of the observatories in the current context. Here is a quote from it:

“In an article published in 2003, Hemmings and Wilkinson attempted to answer this question [regarding the ever increasing creation of observatories in health, which is happening nowadays].

Firstly, these authors consider that the “observation of health” should be done by Public Health. Secondly, they also consider that the document published in 1974 by the then Minister of Health of Canada, Marc Lalonde - “A new perspective on the health of Canadians” – marks the beginning of the agenda of the “New Public Health”, adopted by many western countries, and was characterized by an increasing orientation for the prevention of premature death, incapacity, and for the development of healthy public policies, based on evidence.”



## RPA WAS INTRODUCED AT THE LAST ICOR MEETING

→ On May 9 and 10, in the headquarters of FDA, in Silver Spring, Maryland, USA, there was a meeting of the International Consortium of Orthopaedic Registries (ICOR), where Dr. José Costa Ribeiro represented the Portuguese Arthroplasty Register (RPA). **This meeting was attended not only by representatives of other orthopaedic registries, as well as several stakeholders (namely North-American ones), representing the different interests at stake in the health market.**

“The first day of the meeting was very participated, and was dedicated to the introduction of the various registries and to the exchange of points of view with other health players who were represented; the second day was geared solely towards debate between the registries, with the goal of finding strategies to maintain a high quality of the registries, and find a common and universal language, launching, at the same time, the groundwork

for a closer collaboration in the future”, says José Costa Ribeiro. He also highlights this was a “successful experience” for RPA: “It called attention to our register, and besides that, we confirmed that RPA has almost all of the requirements needed in a register, and that is important, being one of the most recent registers. We will have to iron out some rough edges; one of which has to do with the clarification and definition of laterality, as it was decided to adopt the Charnley criteria.”

José Costa Ribeiro also points out that, in this ICOR meeting, he received an invitation for RPA to be represented in the 1st International Congress of Arthroplasty Registries, sponsored by the Norwegian Registry, which will take place in Bergen, Norway, next year. “It is a invite that honors us and that will bring us visibility”, says the Chairman of RPA. ☐

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**Nome:** Xarelto. **Composição:** Cada comprimido revestido por película contém 10 mg de rivaroxabano. **Forma Farmacéutica:** Comprimido revestido por película. **Indicações terapêuticas:** Prevenção do tromboembolismo venoso (TEV) em doentes adultos submetidos a artroplastia electiva da anca ou joelho. **Posologia e modo de administração:** 10 mg de rivaroxabano, administrados, por via oral, uma vez ao dia. A posologia inicial deve ser administrada 6 a 10 horas após a cirurgia, desde que a hemostase tenha sido estabelecida. A duração do tratamento depende do risco individual do doente para tromboembolismo venoso, a qual é determinada pelo tipo de cirurgia ortopédica. Grande cirurgia da anca: tratamento de 5 semanas. Grande cirurgia do joelho: 2 semanas. Se for esquecida uma dose, o doente deverá tomar Xarelto imediatamente e depois continuar no dia seguinte com a toma uma vez ao dia, tal como anteriormente. Pode ser tomado com ou sem alimentos. Não é necessário ajuste posológico: compromisso renal ligeiro ou moderado, doentes com outras doenças hepáticas, doentes com idade superior a 65 anos, sexo, peso corporal. Não é recomendada a utilização em doentes com taxa de depuração da creatinina < 15 ml/min. Está contra-indicado em doentes com doença hepática associada a coagulopatia e risco de hemorragia clinicamente relevante. Pode ser utilizado com precaução em doentes com cirrose e com compromisso hepático moderado (Child Pugh B) se não estiver associado a coagulopatia. Crianças e adolescentes: não é recomendada a sua utilização. **Contra-indicações:** Hipersensibilidade à substância activa ou a qualquer um dos excipientes. Hemorragia activa clinicamente significativa. Doença hepática associada a coagulopatia e risco de hemorragia clinicamente relevante. Gravidez e lactação. **Advertências e precauções especiais de utilização:** Risco hemorrágico, compromisso renal, compromisso hepático, punção ou anestesia espinal/epidural, doentes com risco aumentado de hemorragia. Os doentes com problemas hereditários raros de intolerância à galactose, deficiência de lactase Lapp ou má absorção de glucose-galactose não devem tomar este medicamento. Não é recomendado nos doentes submetidos a cirurgia por fractura da anca. **Interações medicamentosas:** Inibidores do CYP3A4 e da gp-P: não é recomendada em doentes submetidos a tratamento sistémico concomitante com antimicóticos azólicos tais como cetoconazol, itraconazol, voriconazol, posaconazol ou inibidores da protease do VIH; Anticoagulantes: deve ter-se precaução se os doentes são tratados concomitantemente com quaisquer outros anticoagulantes; AINES/ inibidores da agregação plaquetária: deve ter-se precaução nos doentes tratados concomitantemente com AINES (incluindo ácido acetilsalicílico) e inibidores da agregação plaquetária; Indutores do CYP3A4; Os parâmetros de coagulação (ex.: TP, aPTT, HepTest) são afectados. **Efeitos indesejáveis:** Aumento da GGT, aumento das transaminases, anemia, náuseas, hemorragia pós-intervenção, aumento da lipase, aumento da amilase, aumento da bilirrubina no sangue, aumento da HDL, aumento da fosfatase alcalina, taquicardia, trombocitemia, síncope, tonturas, cefaleia, obstipação, diarreia, dores abdominais e gastrointestinais, dispepsia, boca seca, vômitos, compromisso renal, prurido, exantema, urticária, contusão, dor nas extremidades, secreção da ferida, hemorragia, hemorragia do tracto gastrointestinal, hematúria, hemorragia do tracto genital, hipotensão (incl. diminuição da pressão arterial, hipotensão intraoperatória), hemorragia nasal, edema localizado, edema periférico, sensação de mal-estar (incl. fadiga, astenia), febre, aumento da bilirrubina conjugada (com ou sem aumento concomitante da ALT), dermatite alérgica, anomalias da função hepática, hemorragia num órgão crítico (ex.: cérebro), hemorragia adrenal, hemorragia conjuntival, hemoptises, hipersensibilidade, icterícia. Número da A.I.M.: 5132956, 5132964, 5132972. Data de revisão do texto: Setembro 2008. \* - redução do risco relativo. **Referências:** 1. J Bone Joint Surg (Br) 2009; 91-B:636-644; 2. N ENGL J MED 2008; 358:2776-2786. 3. RCM

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L.PT.GM.09.2010.0082