

A DESIGN REVIEW FOR DEVELOPMENT OF ARTIFICIAL SPHINCTER PROTOTYPE

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Abstract. *Colorectal cancer reaches the segment of large intestine and can also be found in rectum. It is ranked in Brazil as one of the most common types of cancer among men and women. In this work a design review was carried out with the main objective of verifying the best application for development of an artificial sphincter for individuals suffering from colorectal cancer. The proposed mechanical design was considered satisfactory since it was evidenced that this new artificial sphincter prototype function should be designed to avoid leakage of liquid feces as well as digestion gases. As conclusions, prosthesis operation should not be targeted as an application only for individuals who use the colostomy bag, but also for those who opted for another type of surgery to avoid colostomy.*

Keywords: *Colorectal cancer. Sphincter. Prototype. Surgeries.*

1. INTRODUCTION

According to the Brazilian National Cancer Institute (INCA), the Colorectal cancer reaches the segment of the large intestine and can also be found in the rectum, and is the 3rd most common type of cancer found in men and the 2nd most common in women. Surgical indications are based on items such as the height and the state of the cancer, the patient's situation and may also vary according to the surgeon preferences and the patient, the position where the cancer is located and survival rates. The main objective of this study is to verify the best application for the mechanical design of an artificial sphincter for use in individuals affected by colorectal cancer. It can be noted through the literature review that even with the evolution of surgeries and techniques, fecal incontinence and constipation affect both ostomy patients and patients with colorectal cancer operated by surgery without ostomy. It was also evidenced the materials used in prototypes, such as Habr-Gamma, the mechanical suture technique used in the models of staplers by surgeons and the rise of new surgeries for the operation of cancer. It is concluded to date that the design of a new prototype in a three-dimensional program of an artificial sphincter should be adjusted to avoid leakage of liquid feces and gases and that this should not only target the individual making use of the bag colostomy, but also those who opted for other type surgery to avoid colostomy. It is hoped that with this the application field of the proposed model can be extended to both ostomized and non ostomized.

2. COLORECTAL CANCER

Colorectal cancer affects the segment of the large intestine and can also be found in the rectum (INCA, 2017); however, it is worth mentioning that both cancer and surgery can be avoided if it is detected early, if it has a healthy diet and familiar history (INCA, 2017). According to the National Cancer Institute (INCA, 2016) in 2012 the expectation of cancer incidence in the Southeast region of Brazil was in 22 cases per 100,000 men and 23 cases per 100,000 women, with the last finding of new cases in Brazil were 16,660 men and 17,620 women, ranking as the third most common type in men and the second in women.

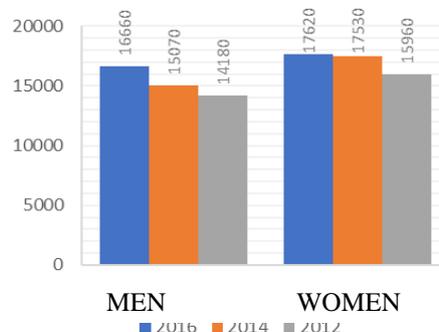


Figure 1. Proportional distribution of colon and rectum cancer by sex, except non-melanoma skin in Brazil. Source: INCA, 2017. Adapted by the author

In the European continent, the rectum cancer is the second type of cancer that causes death (Campelo and Barbosa, 2016) and in the ranking prepared by researchers from the International Agency for Research on Cancer (IARC), shows that Brazil follows the world scenario, according to Ferlay *et al.* (2012) the colorectal cancer also appears as the 3rd most common type in men and the 2nd in women oscillating their position in some regions to the 4th position. For Bray *et al.* (2017) the projection of new cases of this type of cancer should reach a value close to 43 thousand in 2020.

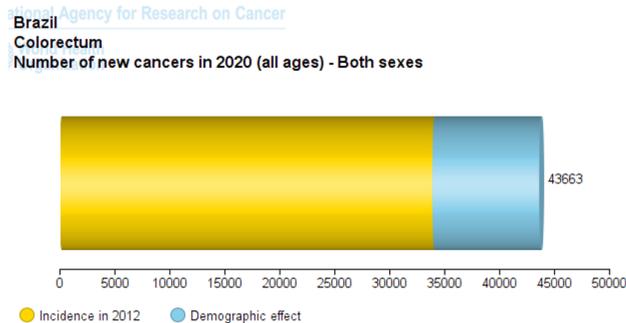


Figure 1. Estimation of new cases of colon and rectum cancer, except for non-melanoma skin for Brazil in 2020.

Source: Bray *et al.*, 2017. Adapted by the author

2.1 Abdominoperineal Resection Surgery for colorectal cancer and bowel collecting bags

Abdominoperineal Resection Surgery (APR) is a complex surgical procedure for cases of rectal cancer in the lower part of the rectum that when removed removes the organ affected by the cancer and can result in definitive abdominal colostomy due to the removal of the rectum, cervix and anus (Silva *et al.*, 2016; Doherty, 2012).

After the definitive abdominal colostomy, an opening is generated close to the abdomen, in order to eliminate the feces that are no longer eliminated by the anus, and the patient who undergoes this type of surgery becomes an "ostomy" (National Supplementary Health Agency, 2009). The ostomate has no more control over the bowel movements and with this should make use of intestinal collection bags (Hollister, 2016).

Intestinal bags have the function of collecting the individual's feces and can be found in a range of variations from those that avoid odors, visual malaise to those that emit noises and can be divided basically into: drainable and non-drainable; transparent and opaque; one piece and two pieces. For Gomes *et al.* (2005) the main intention of these varieties is to make the individual can have a better social life, allow the return of libido, decrease depression and also the sexual relationship. For Maruyama *et al.* (2009); Reis (2014) the use of scholarship represents to the individual the disfigurement before a society that values the perfect body, a fact that requires a rearrangement of his family, professional and cultural life.

3. Demand justification

In order to verify the demand for research the largest field to be researched was chosen, the oncological area, and sequentially analyzed the data from INCA since 2012 to verify the locations of the human body with the highest incidence of cancer. After this step the five major cancers were found according to INCA and it was sought to determine which of these affected both men and women, thus eliminating prostate, breast and cervical cancer. After this stage, trachea, bronchial and lung cancer and colon and rectum cancer remained as options, and these two items were considered as presuppositions, which were already analyzed in the market and in the academic environment regarding evolutions, solutions, researches and prostheses since 2012. It was verified a great evolution on the cancer of rectum in this period of 6 years in the academic area with evolutions in the type of surgery culminating in the practical area in better results and in the question of prosthesis was noticed the existence of a model already in use, however with needs of improvement due to reports found in scientific articles.

After the request was found, some attempts were made to contact institutions to verify lessons learned from the prosthesis and surgeries, to carry out a risk analysis before it and to analyze the best practices performed by these institutions. It was hoped that brainstorming could be done together, but due to scheduling conflicts, such activity was not yet possible.

4. Methodology

In this work a design review was carried out with the main objective of verifying the best application for development of an artificial sphincter for individuals suffering from colorectal cancer. A proposed computational design model was achieved and evaluated according to the requirements and parameters collected during review.

4.1 Techniques for individuals with colorectal cancer undergoing APR

Aiming to increase freedom in the use of the bag and the conviviality of ostomates with other individuals, some techniques were improved, one of them being self-irrigation, which according to Maruyama *et al.* (2009), arose in 1927 and allows the individual to increase their intestinal control through the intestinal clean out. After training with nurses, it is possible for the patient to use this technique at home, thus reducing the amount of exchange of bags. Self-irrigation does not eliminate the need to use the collection bag, as this technique only allows the person to feel safer with faecal emptying at home (Silva *et al.*, 2016; Maruyama *et al.* (2009)).

Chemoradiotherapy has also been indicated as one of the recent techniques under study that can be used to treat rectum cancer after surgery, but still requires a more specific study on the cases that can be treated by this practice (Habr-Gama, Julião and Perez 2017; Sole, Calvo, 2014).

4.2. Alternative Surgeries to APR for Colorectal Cancer

Unlike the techniques, which aim to minimize the problem faced by the operated patients, other types of surgery can be performed and according to Campelo and Barbosa (2016); Santos (2012); Sole and Bald (2014) The items that can define the type of surgery to be performed vary according to the height and the state of the cancer, the patient's situation, the surgeon's and patient's preference, the position where the cancer is and the results of survival.

With advances in the surgical area in 1991, it was possible for patients to opt for the surgical procedure of "abdominoperineal amputation plus perineal colostomy with irrigation". This surgery consists of maintaining the evacuation near the place where the anus existed through an opening in the perineum (Silva 2014). This aperture in the perineum makes use of the same principle of the pouch colostomy, as it allows the bowel to be connected to an outlet for evacuation, but instead of the pouch in this case an invagination is created by means of a suture in the neck in order to create something close to the anal sphincter (Silva, Hayck, Deoti, 2014; Gama et.al, 2014).

The lower anterior resection (LAR) began to be practiced after 40 years of APR, this surgery is applicable in cases where the cancer is in the middle and upper part of the rectum and avoids the use of a definitive colostomy bag (Campelo, Barbosa, 2016).

A new surgery called total mesorectum excision (TME), which according to Bustamante (2017) "[...] consists of precise and careful dissection around the rectum in the pelvis aiming at preserving the visceral fascic integrity of the rectum". The TME was introduced after the advent of LAR because the latter was unable to treat low rectal cancer, thereby causing it to return to APR to obtain a treatment and consequently return to the use of the colostomy bag. For Bustamante (2017); Campelo and Barbosa (2016), TME decreased the recurrence rate of colorectal cancer and increased the survival rate in the operated patients.

New forms of surgery are being discovered as the transanal TME that does not require an abdominal incision to withdraw the tumor, since the removal of the tumor is done by the anus itself (Colono, 2016, Campelo and Barbosa, 2016). The use of laparoscopy, which is a type of surgery with fewer incisions, has been integrated into the new types of surgeries because it allows less invasive surgeries and faster healing (Araujo, 2003).

Stapler enhancement in TME surgeries contributed along with mechanical anastomoses, which were done with manual sutures, to reduce APR (Neves; Ferreira, Cruz, 2005; Bonardi *et al.*, 2003).

Even with the advancement of these new surgeries APR and LAR still present as an option in cases of radical resection (Campelo and Barbosa, 2016; Correa, 2012; Cruz, et.al, 2008).

5. Results and computational design model

The mechanical design considered all requirements such anatomic placement and digestive functions for patients safety and quality of life during treatment of Colorectal Cancer. A computational design model was obtained by Computer Aided Design software AutoCAD (Autodesk Inc., San Rafael, CA), as seen on Figure 3.

As the project proposal is the elaboration of an artificial sphincter the shape proposed in the model was elaborated with characteristics close to the size of the natural sphincter and its cylindrical shape. The proposed Stent format (shown in Figure 3), besides having the desired cylindrical shape for the project, was chosen due to the fact that the area of prostheses and research aimed at the heart and arteries of the same are well developed besides possessing a wide range of information, articles and reports of surgeries published on these which will guide future choices of materials and other necessary points.

The use of magnetite super paramagnetic nanoparticles is related to the biocompatibility of the same and the facility to grow it in the laboratory, since the staplers are used in the current surgery of the rectum.

The initial prototype will be designed for use in dead tissue by hybrid technique so that a preliminary study on the functionality of the same is possible so that later can be applied in living organisms.

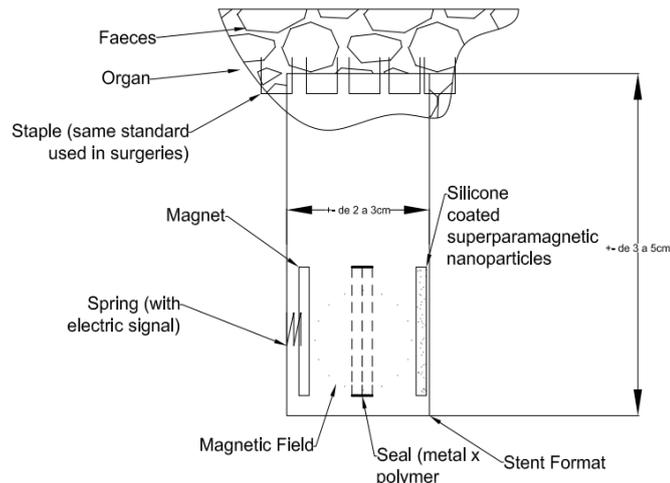


Figure 3. Computational design model of the artificial sphincter in AutoCAD. Authorship

The artificial sphincter prototype was inspired in coronary stent design and consists of flexible tubing with length of 30 to 50 mm and diameter of approximately 25 mm (± 5 mm of distention). The valve actuator is based on spring principle with metal super magnet nanoparticles coated with silicon. Each actuator is positioned surrounding the prosthesis to promote the sphincter sealing.

After computational conception of the design model it was possible to study the artificial sphincter placement and interaction with local environment. It was located in the injured portion of the colon and rectum in order to collect feces sealing the sphincter and it is anchored by surgical metallic clamps, as shown in Figure 3.

5.1. Preservation of the sphincter in the colorectal cancer and incontinence

For Campelo and Barbosa (2016) preservation of the sphincter in low rectal cancer is the key to maintaining good bowel function and not developing low resection syndrome. The low resection syndrome affects 30 to 70% of the patients who underwent surgery and is characterized by fecal incontinence, pain and urgency to evacuate. Silva, et. (22%), anorectal pain (34%), and constipation (30%) were found in all of them.

Habr-Gama (2000) found through initial experiments using an artificial anal sphincter model in silicone, similar to the artificial sphincter used in cases of urinary incontinence, that the escape of liquid feces and gases still prevailed at the end of the study and that the model should be improved. Pimentel (2015) found that a careful selection of individuals is required for artificial sphincter use, that the experiments performed in 30% of the patients under study demonstrated difficulty in defecating requiring clean out to assist the action and that there is a concern with the rate of infection, a fact that Wexner (2009) already evidenced in 41.2% of his sample.

Fischer et. al (2010) found that more than 20% of patients undergoing LAR had to redo a new surgery to use the colostomy bag because the sphincter did not live up to LAR. For Cornish et. al (2007), Cochrane and Wille (2005), their samples resulted in an equal quality of life index or with an almost insignificant difference between LAR and APR surgery. Norton, Burch and Kamm (2005) found that most of their sample was satisfied with the opening of a stoma for fecal continence in the face of faulty incontinence of the sphincters.

6. Final considerations

Based on the facts, the fall trend of APR and the advent of less invasive surgery with staplers and laparoscopies, it was observed that the problems evidenced with constipation and with fecal incontinence have a significant incidence in patients with colorectal cancer both for those who do use of the colostomy bag as those who do not. Due to this observation the prosthesis design should be expanded and adjusted to this segment instead of just being restricted to the patient with a colostomy bag, considering that the surgery that generates the use of the colostomy bag tends to be avoided by the surgeons due to the rate of recurrence of cancer at the site and the survival rate.

As an initial model the design of prosthesis was generated, in which the good practice already used by the surgeons in the use of the stapler for the connection to the part was chosen. For the selection of the seal, the ANSI-B16-104 standard, which is used for valve sealing, is used as a standard, focusing on class IV or V of said standard, since these classes allow leaks of 0.01% of maximum flow capacity and $0.0005 \text{ cm}^3 / \text{min}$ per inch of orifice diameter due to the findings of gas leakage and incontinence of the surgeons in their studies.

REFERENCES

- ARAÚJO, S. E. A. *et al.* Conventional approach x laparoscopic abdominoperineal resection for rectal cancer treatment after neoadjuvant chemoradiation: results of a prospective randomized trial. *Rev. Hosp. Clín. Fac. Med. S. Paulo*, v.58, n.3, p.133-140, 2003. Disponível em: <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0041-87812003000300002&lng=en&nrm=iso>. Acessado em: 12 Nov. 2017.
- BRAY, F.; REN, J., S.; MASUYER, E.; FERLAY, J.; Estimates of global cancer prevalence for 27 sites in the adult population in 2008. *Int J Cancer*. 2013 Mar 1;132(5):1133-45. doi: 10.1002/ijc.27711. Epub 2012 Jul 26.
- BUSTAMANTE, L., L., A.. Avaliação de variáveis associadas à redução do número de linfonodos em espécime cirúrgico de câncer de reto após quimiorradioterapia neoadjuvante. 2017. Tese (Doutorado em Ciências em Gastroenterologia) - Faculdade de Medicina, Universidade de São Paulo, São Paulo, 2017. Disponível em: <<http://www.teses.usp.br/teses/disponiveis/5/5168/tde-04082017-100412/>>. Acessado em: 12 Nov. 2017.
- CAMPELO, P.; BARBOSA, E. Functional outcome and quality of life following treatment for rectal cancer, In *Journal of Coloproctology*, Volume 36, Issue 4, 2016, Pages 251-261, ISSN 2237-9363. Disponível em: <https://doi.org/10.1016/j.jcol.2016.05.001>. Acessado em: 12 nov 2017.
- CORNISH, J.,A.; TILNEY, H.,S.; HERIOT, A.,G.; LAVERY, I.,C.; FAZIO, V.,W.; TEKKIS, P.,P.: A meta-analysis of quality of life for abdominoperineal excision of rectum versus anterior resection for rectal cancer. *Ann Surg Oncol* (2007) 14: 2056. Disponível em: <https://link.springer.com/article/10.1245%2Fs10434-007-9402-z>. Acesso em: 11/11/2017
- CRUZ G,M,G; FERREIRA, R,M,R,S; NEVES, P,M.. Cirurgias Para Câncer Retal - Estudo Retrospectivo de 380 Pacientes Submetidos à Cirurgia Para Câncer Retal, ao Longo de Quatro Décadas. *Rev bras Coloproct*, 2005;25(4):309-331.
- CRUZ GMG; ANDRADE MMA; GOMES DMBM; CONSTANTINO JRM; CHAMONE BC. Estoma & Câncer Retal: Revisão de 195 Estomas Realizados em 380 Pacientes Portadores de Câncer Retal. *Rev Bras Coloproct*, 2008;28(2): 193-203.
- DOHERTY, G., M. *Current Diagnóstico e Tratamento: Cirurgia*. Mc Graw Hill. Disponível em: <https://books.google.com.br/books?id=Fz2KDgAAQBAJ&pg=PT2094&lpg=PT2094&dq=submetidos+a+LAR&source=bl&ots=HaMOytcjiq&sig=svtZDuUp9ilDJgRkkm2azdj0p0&hl=pt-BR&sa=X&ved=0ahUKEwiCyuzO87PUAhUBxpAKHeQECbsQ6AEIKjAB#v=onepage&q=submetidos%20a%20LAR&f=false>. Acesso em:07/06/2017
- FERLAY J, SOERJOMATARAM I, ERVIK M, DIKSHIT R, ESER S, MATHERS C, REBELO M, PARKIN DM, FORMAN D, BRAY, F.. *GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11* [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>, accessed on day/month/year
- FISCHER, A.; TARANTINO, I.; WARSCHKOW, R.; LANGE, J.; ZERZ, A.; HETZER, F.,H.; Is sphincter preservation reasonable in all patients with rectal cancer?. *International Journal of Colorectal Disease*. 2010. Disponível em: <https://link.springer.com/article/10.1007%2Fs00384-010-0876-y>. Acesso em:11/11/2017
- GOMES, E. G. A. ; BRANDT, C. T. ; JUCA, M. J. ; MENEZES, H. L. . Colostomia continente com esfínter artificial de silicone: estudo em cães.. *Acta Cirúrgica Brasileira*, São Paulo, v. 18, n.6, p. 537-541, 2003. LISBOA, A.H.. Resíduos. In: Eugênio Marcos Andrade Goulart. (Org.). *Navegando o Rio das Velhas das Minas aos Gerais v.2*. Belo Horizonte: Projeto Manuelzão, 2005, v. 2, p. 407-446.
- GAMA, R. C.; ET.AL. Perineal colostomy: an option in the treatment of inferior rectal and anal canal cancer. In *Journal of Coloproctology*, Volume 34, Issue 1, 2014, Pages 4-8, ISSN 2237-9363. Disponível em: <https://doi.org/10.1016/j.jcol.2013.12.004>. Acesso em 12 Nov. 2017.
- HABR-GAMA A., JORGE JM. O esfínter anal artificial no tratamento da incontinência grave: descrição de técnica e resultados preliminares _ *Rev Bras Coloproct*, 2000; 20(4): 217-222.
- HOLLISTER. Controlando a sua Ostomia. Disponível em: http://www.hollister.com/~media/files/pdfs-for-download/ostomy-care/understanding-your-colostomy_923054-1216.pdf. Acessado em: 07/06/2017.
- INCA – Instituto Nacional de Câncer Jose Alencar Gomes da Silva – Câncer colorretal. Disponível em: <http://www2.inca.gov.br/wps/wcm/connect/tiposdecancer/site/home/colorretal>. Acessado em: 05/06/2017.
- MARUYAMA, S., A. T.; BELLATO, R.; PEREIRA, W., R.; BARBOSA, C. S.; NAVARRO, J. P . Auto-irrigação - uma estratégia facilitadora para a reinserção social de pessoas com colostomia. *Revista Eletrônica de Enfermagem*, v. 11, p. 665-673, 2009.
- NATIONAL SUPPLEMENTARY HEALTH AGENCY (ANS). Disponível em: http://www.ans.gov.br/images/stories/noticias/pdf/p_sas_400_2009_ostomizados.pdf
- NORTON, C.; BURCH, J.; KAMM, M. A.. *Dis Colon Rectum* (2005) v.48: pg.1062. Disponível em: <https://doi.org/10.1007/s10350-004-0868-5>
- PACHLER, J.; WILLE-JORGENSEN P.; Quality of life after rectal resection for cancer, with or without permanent colostomy. Disponível em: <https://www.ncbi.nlm.nih.gov/pubmed/23235607>. Acesso em 1/11/2017

- PIMENTEL, J. M.; DUARTE, A.; PATRÍCIO, J.. O esfíncter Anal Artificial no Tratamento da Incontinência Fecal Severa. Vol. 1 N°2 Maio/Agosto 2004; Pág. 12/19. Disponível em: http://www.spcoloprocto.org/uploads/7_artigo_original_2.pdf
- REIS, DANIELLE FREITAS DOS. Novas tecnologias para o cliente ostomizado: refletindo a atuação do enfermeiro a partir da literatura. 2014. 43 f. Trabalho de Conclusão de Curso (Especialização em Linhas de Cuidado em Enfermagem – Doenças Crônicas Não Transmissíveis) – Universidade Federal de Santa Catarina, Florianópolis, 2014.
- SILVA, A. C.; ESPINDOLA, B. ; TOMIM D.H ; ZALEWSKI, W. ; FERRERO, C. A. ; LEE, H. D. ; WU, F. C. . Estudo da grandeza física área sob a curva pressão vs. tempo do exame manometria ano-retal em relação à pressão máxima de contração voluntária e à capacidade de sustentação de pacientes continentes e incontinentes fecal grau III. In: XIX Encontro Anual de Iniciação Científica - EAIC, 2010, GuaAPRuava. Encontro Anual de Iniciação Científica, 2010.
- SOLE, CLAUDIO V; CALVO, FELIPE A.. In Regard to Habr-Gama *et al.* International Journal of Radiation Oncology Biology Physics, Volume 89 , Issue 4, 932 – 933. 2014.
- SILVA, A., L.; HAYCK, J.; DEOTI, B. Perineal colostomy: an alternative to avoid permanent abdominal colostomy: operative technique, results and reflection. ABCD, arq. bras. cir. dig., São Paulo , v. 27, n. 4, p.243-246, Dec. 2014. Available from <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-67202014000400243&lng=en&nrm=iso>. Acesso em 12 Nov. 2017. <http://dx.doi.org/10.1590/S0102-67202014000400004>.
- SILVA, T., B.; OLIVEIRA, L., A.; CÔRTEZ, B., J., W.; LEMOS, C., R., R.; SANTOS R., M.; FREITAS, A., H., A.; LUZ, M., M., P.; CONCEIÇÃO, S., A.; COSTA, L., M., P.; QUEIROZ, F., L.; SILVA, R., G.; LACERDA, F., A. Excisão Total do Mesorreto em Pacientes com Câncer Retal - Estudo de 85 pacientes. Rev Bras Coloproct, 2003;23(1):53-60
- SILVA, E., S.,; CASTRO, D., S.; GARCIA, T., R.,; ROMERO, W., A., G.; PRIMO, C., C.. Care technology to people with colostomy: diagnosis and nursing interventions. Reme. Revista mineira de enfermagem, v. 20, p. 931, 2016. da C. M 2006.