

UNIVERSIDADE ESTADUAL DO NORTE FLUMINENSE DARCY RIBEIRO

MATHEUS ROBERTO DA MOTA COSTA

**ESTUDO PRELIMINAR DE VIABILIDADE DE UM NOVO DISPOSITIVO
CIRÚRGICO (LIGATIE®) NA LIGADURA DO MESOVÁRIO EM CADELAS**

CAMPOS DOS GOYTACAZES - RJ

2016

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Dissertação apresentada ao Centro de Ciências e Tecnologias Agropecuárias da Universidade Estadual do Norte Fluminense Darcy Ribeiro, como um dos requisitos para obtenção do título de Mestre em Ciência Animal.

ORIENTADOR: Prof. Dr. André Lacerda de Abreu Oliveira

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BANCA EXAMINADORA

Prof. Dr. Renato Moran Ramos (Doutor em Ciência Animal – UNIG)

Prof^a. Dr^a. Fernanda Antunes (Doutora em Medicina – UENF)

Dr^a Daniela Fantini Vale (Doutora em Ciência Animal – UENF)

Prof. Dr. André Lacerda de Abreu Oliveira (Doutor em Medicina - UENF)
(Orientador)

DEDICATÓRIA

Dedico à minha filha Helena, principal fonte de inspiração e motivação para ser cada vez melhor em qualquer coisa que eu faça.

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RESUMO

A ligadura do mesovário em cadelas apresenta risco de complicações e está associada a estímulos nocivos intensos. Um implante absorvível apresentando um sistema de autotravamento foi desenvolvido para a utilização em cirurgia como uma alternativa a ligadura tradicional com fio de sutura. O estudo teve como objetivo testar a viabilidade da ligadura do pedículo ovariano canino com este novo implante e comparar seu desempenho com o fio cirúrgico. No total, 45 cadelas intactas foram submetidas à ovário-histerectomia eletiva. Em 21 cadelas o implante absorvível foi utilizado para a ligadura do mesovário e em 24 cadelas de controle utilizado fio de sutura com uma ligadura circular. O peso médio dos cães do implante foi de $10,7 \pm 5,6$ kg (intervalo de 3,5-22,0), e peso médio de cães de controle foi de $12,8 \pm 6,4$ kg, (intervalo de 4,1-27,0). O peso corporal dos cães não diferiu entre os grupos ($P = 0,25$). No total, 42 pedículos ovarianos foram ligados com sucesso com o implante. Em uma cadela do grupo controle foi observada hemorragia intraoperatória no pedículo ovariano esquerdo. O mesovário foi religado e foi confirmada a hemostasia. Todos os animais tiveram evolução favorável. O tempo de ligação do mesovário foi significativamente reduzido ($P = 0,02$) através da utilização do implante em relação à ligadura ($3'28'' \pm$ tempo de $1'05''$ e $5'29'' \pm 3'54''$, respectivamente). A duração total da cirurgia diferiu entre os grupos ($P = 0,02$), com uma duração mais curta da cirurgia quando se utilizou o implante ($15'56'' \pm 2'47''$ e $20'39'' \pm 8'58''$, grupo de estudo em relação ao grupo controle, respectivamente). Em ambos os grupos, o tempo de cirurgia e o tempo necessário para ligar o pedículo ovariano foram mais longos em cães maiores do que cães menores. Os resultados deste estudo sugerem a viabilidade do implante para ser utilizado na ligadura do mesovário canino. Em comparação com a ligação de sutura tradicional, o tempo para ligar o pedículo ovariano e da duração da cirurgia foi significativamente reduzido, com o implante. Mais tempo foi necessário para realizar as cirurgias em cães maiores.

Palavras-chave: dispositivo médico, Glicólido, trimetilenocarbonato, pedículo ovariano, ovário-histerectomia.

ABSTRACT

Ligation of the mesovarium in female dogs may be cumbersome with risk of complications and is associated with intense noxious stimuli. A resorbable implant, a self-locking loop designed for surgery, was developed as an alternative to traditional ligation. The study aimed to test the feasibility of ligating the canine ovarian pedicle with the implant and to compare its performance to traditional suture ligation. In total 45 intact female dogs destined for elective ovariohysterectomy were included. In 21 dogs the new resorbable implant was used to ligate the mesovarium, and in 24 control dogs traditional suture was used with one encircling ligature. Mean weight of implant dogs was 10.7 ± 5.6 kg (range 3.5 – 22.0), and mean weight of control dogs was 12.8 ± 6.4 kg, (range 4.1 – 27.0). The body weight of dogs did not differ between groups ($P = 0.25$). In total, 42 ovarian pedicles were successfully ligated with the implant. In one control dog, intraoperative haemorrhage from the left ovarian pedicle was diagnosed. The mesovarium was re-ligated and haemostasis was confirmed. All dogs recovered uneventfully. The ligation time of the mesovarium was significantly shortened ($P = 0.02$) by using the self-locking implant versus a single ligature ($3'28'' \pm 1'05''$ and $5'29'' \pm 3'54''$, respectively). Total duration of surgery differed between the groups ($P = 0.02$) with a shortened duration of surgery when using the self-locking implant ($15'56'' \pm 2'47''$ and $20'39'' \pm 8'58''$, study group versus control group, respectively). In both groups, duration of surgery and time required to ligate the ovarian pedicle were longer in larger dogs than smaller dogs. The results of this feasibility study suggested the implant can be used to ligate the canine mesovarium. Compared with traditional suture ligation, time to ligate the ovarian pedicle and duration of surgery was significantly reduced with the implant. More time was required to perform surgeries in larger dogs.

Keywords: Medical device, Glycolide, Trimethylene carbonate, Ovarian pedicle, Ovariohysterectomy.

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LISTA DE SIGLAS E ABREVIATURAS

OVH	Ovário-histerectomia
CO ₂	Dióxido de carbono
mmHg	Milímetro de mercúrio
cm	Centímetro
mm	Milímetro
SOR	Síndrome do ovário remanescente

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1. INTRODUÇÃO

Em medicina veterinária a ligadura das estruturas do pedículo ovariano e coto uterino está entre as mais realizadas na prática cirúrgica de pequenos animais e, apesar da grande disponibilidade de materiais disponíveis, a hemorragia Peri e pós-operatória é uma das principais complicações relatadas na realização da ovariopexia (MURARO & WHITE, 2014).

As suturas desempenham um papel fundamental nos procedimentos cirúrgicos, sendo responsáveis por promover hemostasia imediata dos vasos sanguíneos até que o organismo produza hemostasia definitiva (TZIMTZIMIS & PAPAOGLOU, 2012). Até alguns anos a escolha de suturas na prática cirúrgica veterinária se limitava ao uso dos fios de seda, náilon e catgut. Atualmente o cirurgião veterinário tem a sua disposição uma grande variedade de materiais com características e composições distintas, sendo possível a escolha do implante que melhor se adéqua ao procedimento cirúrgico a ser realizado (NEATH, P.J., 2005).

Apesar da boa capacidade dos fios de sutura em promover a hemostasia dos vasos sanguíneos durante a OVH, buscaram-se alternativas que apresentassem melhor eficiência em promover hemostasia ao mesmo tempo em que reduzisse o tempo cirúrgico. Um dos dispositivos utilizados como alternativa, mesmo não sendo considerado cirúrgico, foi a abraçadeira de náilon (HOWE, 2006). Evidenciou-se hemostasia eficiente como resultado da utilização deste dispositivo na OVH, bem como redução do tempo cirúrgico e maior facilidade de execução da técnica. No entanto, foram observadas limitações importantes como a quantidade de tecido a ser ligada junto com as estruturas vasculares, reações teciduais significativas e formação de granulomas, estando estes dois últimos diretamente relacionados com a característica inabsorvível do náilon (MACEDO et al., 2012).

O presente trabalho justifica-se pela necessidade de criação de implantes que apresentem alta eficiência em promover hemostasia, reduzam o tempo cirúrgico e que tenham a capacidade de absorção pelo organismo, resultando em um procedimento cirúrgico mais rápido, eficiente e sem resíduos de implantes, o que pode resultar em complicações em longo prazo.

As hipóteses apresentadas são de que o tempo cirúrgico com a utilização da abraçadeira de poligliconato será menor quando comparado com a utilização do fio de sutura, a hemostasia resultante da utilização da abraçadeira será eficiente e não haverá diferença significativa entre os implantes na ocorrência de complicações pós-operatórias.

Devido à hemostasia eficaz, juntamente com a maior facilidade de execução da técnica e menor tempo cirúrgico durante a realização da OVH obtidos pela utilização da abraçadeira de náilon, objetivou-se neste trabalho avaliar a eficácia de uma abraçadeira confeccionada em poligliconato, material absorvível, para a realização da ligadura do mesovário em cadelas e comparar sua eficácia com o fio de sutura confeccionado com o mesmo material.

2. REVISÃO DE LITERATURA

2.1 ANATOMIA CIRÚRGICA

Os ovários das cadelas apresentam formato oval, medindo de 0,5 a 1,5 centímetros de comprimento e se situam próximo ao polo caudal dos rins, sendo o direito ligeiramente mais cranial quando comparado ao esquerdo. Um envoltório duplo formado pelo peritônio denominado bursa ovariana envolve o ovário e o mantém aderido à parede abdominal através do mesovário, uma continuação do ligamento largo do útero. O ligamento largo ainda origina o ligamento suspensor do ovário, que se estende cranialmente até as duas últimas costelas e se conecta na porção ventral do ovário. O ligamento próprio do ovário, por sua vez, se origina do ligamento suspensor e se estende da porção caudal do ovário à região cranial do corno uterino (FINGLAND, 1996).

A vascularização dos ovários ocorre através das artérias ovarianas, que se ramificam diretamente da aorta abdominal e chegam ao ovário através do mesovário. Promovem ainda a vascularização da cápsula renal e se anastomosam nas artérias uterinas, fornecendo ainda suporte sanguíneo à porção cranial do corno uterino. A drenagem sanguínea é realizada pelas veias ovarianas, sendo a drenagem do ovário direito realizada diretamente para a veia cava caudal, enquanto a esquerda adentra a veia renal esquerda (NELISSEN & WHITE, 2010).

O útero é formado pela cérvix, corpo uterino e corno uterino direito e esquerdo. Fica aderido à região dorsolateral da parede abdominal através do mesométrio, que é derivado do ligamento largo. O ligamento redondo do útero se estende da porção cranial do corno uterino até o anel inguinal profundo (BARROS et al., 2009).

O aporte vascular do útero é realizado pelas artérias uterinas, que se ramificam da artéria pudenda interna se deslocando através do mesométrio e irrigando a região da cérvix, vagina, corpo uterino e porção caudal dos cornos uterinos até se anastomosar com as artérias ovarianas. A drenagem sanguínea é realizada pelas veias uterinas que seguem o mesmo trajeto das artérias (STONE et al., 1998).

2.2 TÉCNICA CIRÚRGICA

A gonadectomia, ou castração, é o procedimento cirúrgico mais realizado na prática de pequenos animais, sendo seu principal objetivo tornar um animal estéril através da remoção de partes de seu sistema reprodutor (TREVEJO et al., 2011).

Entre os métodos descritos para a realização deste procedimento estão a ovariectomia e a ovário-histerectomia. Mesmo a ovariectomia sendo considerada a técnica de escolha, principalmente pelo menor tempo cirúrgico, a ovário-histerectomia é a técnica mais aceita e praticada, pois resulta na remoção dos ovários juntamente com o útero, prevenindo o surgimento de doenças uterinas (VAN GOETHEM et al., 2006).

2.2.1 Celiotomia

Para a realização do procedimento cirúrgico o paciente é posicionado em decúbito dorsal e a região abdominal é preparada assepticamente. A incisão é realizada na linha média ventral, na região retroperitoneal, da cicatriz umbilical ao púbis. O tamanho da incisão cirúrgica pode variar de acordo com a experiência do cirurgião e com a utilização de instrumentos cirúrgicos específicos que auxiliam na localização do útero. Para a localização do ovário esquerdo pode ser utilizada a manobra colônica, enquanto que a manobra duodenal é utilizada para a localização do ovário direito (NELISSEN & WHITE, 2010).

Após a correta localização do ovário deve-se proceder a ligadura do mesovário contendo os vasos ovarianos. Para a realização da ligadura são utilizadas duas pinças hemostáticas que são posicionadas no pedículo ovariano abaixo da bolsa ovariana e uma pinça hemostática acima da bolsa ovariana para impedir o retorno venoso. Após a escolha do implante e a realização da técnica para a ligadura, as pinças hemostáticas são removidas e o pedículo ovariano avaliado quanto à presença de sangramento. Independente da técnica escolhida para a ligadura aconselha-se a abertura da bolsa ovariana para confirmar a remoção completa do ovário (DAVIDSON et al., 2004).

As artérias uterinas são ligadas individualmente abaixo da cérvix utilizando uma sutura transfixante. Após a ligadura são posicionadas pinças Kocher ou Carmalt na região da cérvix e o útero é seccionado. Para reduzir a possibilidade de aderências

em outros órgãos pode ser realizada a omentização do coto uterino através da confecção de uma sutura simples (BOWLTON et al., 2011).

2.2.2 Laparoscopia

O OVH por laparoscopia é uma alternativa ao método tradicional por abertura da cavidade abdominal. É considerada minimamente invasiva e está associada a menores incidências de complicações transoperatórias, menor perda sanguínea, menor estímulo nociceptivo no período pós-operatório e menor tempo de hospitalização quando comparada a OVH tradicional (DAVIDSON et al., 2004).

Para a realização do procedimento cirúrgico o paciente é posicionado em decúbito dorsal e a região abdominal é preparada cirurgicamente. Inicialmente uma agulha de Veress é introduzida no abdômen 2 a 3 centímetros (cm) caudal à cicatriz umbilical para promover um pneumoperitônio utilizando dióxido de carbono (CO₂) até se alcançar uma pressão intra-abdominal de 12 mmHg (BAIRROS et al., 2015).

Em seguida três portais são criados ao longo da linha média ventral. O primeiro portal é feito 5 cm cranial a cicatriz umbilical, uma incisão de 6 milímetros é realizada para a introdução de uma cânula de 6 mm até a cavidade abdominal. Uma ótica de 5mm é introduzida através da cânula para visualizar a criação dos demais portais. Utilizando a ótica como guia, o segundo portal é criado através do aumento da incisão utilizada para introduzir a agulha de Veress 3 a 5 cm caudal ao umbigo. De maneira similar, uma incisão de 10 mm é feita para criar o terceiro portal 2 a 3 cm cranial ao púbis, onde será introduzido um trocarte de 10mm. Deve-se ter cuidado para não perfurar a bexiga durante este procedimento. A posição, o tamanho e a localização dos portais podem variar de acordo com a preferência do cirurgião (NIRANJANA et al., 2013).

A ligadura dos vasos ovarianos pode ser feita de várias maneiras na OVH laparoscópica, incluindo a utilização de fio de sutura com confecção extracorpórea prévia do nó cirúrgico, *clips* vasculares de metal e equipamentos de cauterização vascular. A escolha da técnica varia de acordo com a disponibilidade do equipamento e experiência do cirurgião. Em relação ao tempo necessário para a realização do procedimento a utilização do fio cirúrgico necessita de um maior tempo cirúrgico, seguido do *clip* vascular de metal e por último a cauterização (MAYHEW & BROWN, 2007).

2.3 HEMOSTASIA

A ligadura eficiente do pedículo ovariano compreende uma das etapas mais importantes na realização da OVH, uma vez que a hemorragia é considerada a causa mais comum de morte em pacientes submetidos a OVH (BOWLT et al., 2011).

O objetivo da ligadura do pedículo é obter a oclusão completa dos vasos sanguíneos até que ocorra a hemostasia definitiva. Fatores como manipulação excessiva, tipo de material, técnica utilizada e número de ligaduras e implantes utilizados são fatores que devem ser considerados para que o resultado final do procedimento seja satisfatório (LEITCH et al., 2012).

2.3.1 Fios cirúrgicos

O fio de sutura é o implante mais utilizado para a realização da ligadura dos vasos sanguíneos na OVH, principalmente pela ampla variedade com que são encontrados comercialmente.

Os fios de sutura podem ser confeccionados em material inabsorvível, absorvível natural ou sintético, podendo ainda ser monofilamentar ou multifilamentar. Os materiais absorvíveis são considerados de escolha para a ligadura do pedículo ovariano, pois permanecem por um tempo menor no organismo quando comparados aos inabsorvíveis, porém por tempo suficiente para que seja observada hemostasia definitiva e gerando menor reação tecidual em longo prazo (HÖGLUND, 2012).

Apesar da grande variedade, todos os materiais de sutura são avaliados quanto a características básicas como capacidade de manipulação, grau de reação inflamatória tecidual gerada, custo, resistência à tração na confecção da sutura, tempo até a perda da resistência e segurança do nó confeccionado (NALEWAY et al., 2014). A escolha do fio está diretamente relacionada às características que este apresenta, material com o qual é fabricado e com o procedimento cirúrgico a ser realizado (MARTURELLO et al., 2014).

Observa-se na literatura relatos de realização da OVH utilizando diversos tipos de fios de sutura como Categute cromado (REECE et al., 2012), polidioxanona (SCHWARZKOPF et al., 2014) e náilon (RUBIO et al., 2014).

2.3.2 Abraçadeira de Náilon

Um dos implantes testados como alternativa à utilização dos fios cirúrgicos foram os lacres feitos de náilon, material inabsorvível, que consiste de uma banda flexível acoplada a um mecanismo de bloqueio (figura 1). Diversas pesquisas foram realizadas utilizando esse dispositivo, entre elas a ligadura do pedículo ovariano em cadelas e gatas (CARPENTER, 1973.; BARROS et al., 2009), ligadura dos vasos ovarianos em éguas (COKELAERE et al., 2005), esplenectomia em felinos (ZAGRANISKI, 1980) e nefrectomia parcial em suínos (MCDOUGALL et al., 1993).



Figura 1: Abraçadeira de nylon.

Fonte: <http://valverdeatacadista.com.br/Produto-FERRAGENS-Abraçadeira-de-nylon-ABRACADEIRA-NYLON-BRASFORT---BRANCA-36-X-200MM---EMBALAGEM-COM-100-UNIDADES-versao-63-65.aspx>

Evidencia-se maior rapidez e facilidade na execução dos procedimentos cirúrgicos realizados com a abraçadeira de náilon, no entanto, este dispositivo apresenta limitações importantes como a quantidade de tecido a ser ligada juntamente com as estruturas alvo e a característica inabsorvível do náilon, resultando em reações teciduais significativas (HOWE, 2006). A formação de reações granulomatosas é frequentemente relatada nos pacientes em que foi utilizado este dispositivo, podendo resultar em comprometimento anatômico e fisiológico das estruturas circunvizinhas (MACEDO et al., 2012; MESQUITA et al., 2015).

2.4 COMPLICAÇÕES

Apesar de ser considerado um dos procedimentos cirúrgicos mais comumente realizados na prática cirúrgica veterinária, a OVH apresenta as mesmas complicações que os demais procedimentos em que é necessária a realização de celiotomia, apresentando ainda como complicações específicas o sangramento do pedículo ovariano e artérias uterinas, piometra de coto, síndrome do ovário remanescente, incontinência e formação de granuloma e trajetos fistulosos, principalmente relacionados à utilização de material multifilamentar inabsorvível (BURROW et al., 2004). Apesar de bem conhecidas e relatadas, as complicações mais comuns relacionadas à OVH não apresentaram uma redução significativa em sua incidência nas últimas décadas (BERZON, 1979; BURROW et al., 2004; MURARO & WHITE, 2014). Outras complicações menos comuns incluem trauma ureteral, hidronefrose e hidroureter (MESQUITA et al., 2015).

2.4.1 Hemorragia

Hemorragias relacionadas à OVH têm sido uma das principais complicações relatadas e a principal causa de morte. Os principais vasos relacionados são a artéria ovariana e artéria uterina, estando a hemorragia destes vasos diretamente relacionada com a aplicação incorreta da técnica de ligadura ou falha do implante (MACEDO et al., 2012). Em estudos realizados com alunos de graduação em medicina veterinária evidencia-se que sua principal preocupação ao submeter um paciente à OVH é o sangramento trans e pós-operatório, (BOWLT et al., 2011).

Para que a ligadura seja eficiente, a escolha do nó, seu posicionamento e segurança são primordiais. A segurança do nó utilizado é influenciada por diversos fatores como tipo de material, número de voltas utilizadas na sua construção e o padrão utilizado. Em um estudo onde foram testados diferentes tipos de fios, foi observado que o número de voltas e o tipo de material estão diretamente relacionados com a segurança e a falha do implante, podendo resultar em hemorragias trans e pós-operatórias, (MARTURELLO et al., 2014).

Apesar da grande variedade de nós cirúrgicos descritos na literatura, é de fundamental importância que se escolha o mais adequado e que apresente menor chance de falha em obter hemostasia satisfatória dos vasos e estruturas onde serão

posicionados. Para a ligadura do pedículo ovariano deve-se dar preferência aos nós transfixantes, pois possuem maior resistência e menor probabilidade de deslocamento, principalmente em pedículos ovarianos volumosos (LEITCH et al., 2012).

2.4.2 Fístula

A ocorrência de fístulas está diretamente relacionada com a utilização de material inabsorvível na ligadura dos pedículos ovarianos e coto uterino. Os trajetos fistulosos geralmente se iniciam na região do pedículo ovariano ou coto uterino seguindo em direção à parede abdominal e finalmente até a pele (NELISSEN & WHITE, 2010).

Além da presença de uma fístula na pele, geralmente é possível observar edema e algia na região da parede abdominal lateral e no flanco, quando envolvem o pedículo ovariano, ou na região interna da coxa e inguinal, quando envolvem o coto uterino (DAIGLE et al., 2001).

Os exames de imagem são geralmente utilizados para estabelecer a origem da fístula. O exame radiográfico simples pode não apresentar alteração quando se trata de material radioluscente, podendo ser realizado um fistulograma (figura 2), que consiste na administração de contraste e posterior realização do exame radiográfico. Modalidades avançadas de imagem como a tomografia computadorizada também podem ser utilizadas quando disponível (JOHNSON-NEITMAN et al., 2006).



Figura 2: Identificação do trajeto fistuloso e observação do corpo estranho (seta) após realização de OVH em cadela.

Fonte: (Johnson-Neitman et al., 2006).

2.4.3 Síndrome do ovário remanescente (SOR)

A síndrome do ovário remanescente é uma complicação iatrogênica que ocorre devido a não remoção completa dos ovários durante a OVH (WALLACE, 1991).

Entre as teorias mais aceitas para a ocorrência da SOR estão a não remoção completa do tecido ovariano durante a cirurgia, posicionamento incorreto das pinças hemostáticas e da ligadura no pedículo ovariano e má visualização e exposição do pedículo ovariano, estando esta última diretamente relacionada com o tamanho da incisão cirúrgica na parede abdominal (DE SOUSA OLIVEIRA et al., 2012). Cita-se ainda a queda acidental de um pequeno fragmento ovariano dentro do abdômen no momento de sua remoção. Ao entrar em contato com omento, mesométrio, peritônio ou camada serosa de algum órgão ocorre a revascularização deste fragmento, tornando-o funcional em poucas semanas ou meses (HEFFELFINGER, 2006).

Sinais clínicos clássicos apresentados por animais com SOR incluem a presença de pró-estro e estro, mesmo após OVH, edema de vulva, corrimento vulvar sero-sanguinolento pseudociese e aceite de cópula. Esses sinais podem aparecer de semanas a vários meses após a cirurgia e parecem estar diretamente relacionados com a quantidade de tecido remanescente (SONTAS et al., 2007).

O tratamento de escolha para a SOR é a remoção cirúrgica do tecido ovariano, porém podem ser de difícil identificação e visualização. A celiotomia convencional é a técnica mais utilizada, porém a laparoscopia também pode ser utilizada como alternativa minimamente invasiva (NAIMAN et al., 2014).

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4. CAPÍTULO 1

Title: Ligation of the mesovarium in dogs with a self-locking implant of a resorbable polyglycolic based co-polymer – a study of feasibility and comparison to suture ligation

Author details

Matheus Roberto da Mota Costa¹, André Lacerda de Abreu Oliveira¹, Renato Moran Ramos², Leonardo Waldstein de Moura Vidal¹, Niklas Borg³ and Odd V. Höglund^{3,4*}

¹Department of Animal Clinical and Surgery, Universidade Estadual Norte Fluminense, UENF/RJ, Av. Alberto Lamego, 2000, Campos dos Goytacazes – RJ – Brazil

²Department of Veterinary Surgery and Anaesthesia, Universidade Iguazu - UNIG/RJ, BR-356 / KM 02, Itaperuna - RJ – Brazil

³Resorbable Devices AB, Ormvråksvägen 15, SE-756 52 Uppsala, Sweden

⁴Department of Clinical Sciences, Box 7054, Swedish University of Agricultural Sciences, SE-750 07 Uppsala, Sweden

E-mail addresses:

MRMC MatheusMotaDVM@hotmail.com ORCID: <http://orcid.org/0000-0001-5040-9654>

ALAO LacerdaVet@uol.com.br

RMR RenatoMoran@hotmail.com

LWMV LeonardoWaldstein@gmail.com

NB Niklas.Olov.Borg@outlook.com

OVH Odd.Hoglund@slu.se ORCID: <http://orcid.org/0000-0003-0978-836X>

*Correspondence: Odd.Hoglund@slu.se

Telephone: +46-18-671328 Fax: +46-18-673534

Abstract

Background: Ligation of the mesovarium in female dogs may be cumbersome with risk of complications and is associated with intense noxious stimuli. A resorbable implant, a self-locking loop designed for surgery, was developed as an alternative to traditional ligation. The study aimed to test the feasibility of ligating the canine ovarian pedicle with the implant and to compare its performance to traditional suture ligation.

Results: In total 45 intact female dogs destined for elective ovariohysterectomy and adoption were included. In 21 dogs the new resorbable implant was used to ligate the mesovarium, and in 24 control dogs traditional suture was used with one encircling ligature. Mean weight of implant dogs was 10.7 ± 5.6 kg (range 3.5 – 22.0), and mean weight of control dogs was 12.8 ± 6.4 kg, (range 4.1 – 27.0). The body weight of dogs did not differ between groups ($P = 0.25$).

In total, 42 ovarian pedicles were successfully ligated with the implant. In one control dog, intraoperative haemorrhage from the left ovarian pedicle was diagnosed. The mesovarium was re-ligated and haemostasis was confirmed. All dogs recovered uneventfully.

The ligation time of the mesovarium was significantly shortened ($P = 0.02$) by using the self-locking implant versus a single ligature ($3'28'' \pm 1'05''$ and $5'29'' \pm 3'54''$, respectively). Total duration of surgery differed between the groups ($P = 0.02$) with a shortened duration of surgery when using the self-locking implant ($15'56'' \pm 2'47''$ and $20'39'' \pm 8'58''$, study group versus control group, respectively).

In both groups, duration of surgery and time required to ligate the ovarian pedicle were longer in larger dogs than smaller dogs.

Conclusion: The results of this feasibility study suggested the implant can be used to ligate the canine mesovarium. Compared with traditional suture ligation, time to ligate the ovarian pedicle and duration of surgery was significantly reduced with the implant. More time was required to perform surgeries in larger dogs.

Keywords: Medical device, Glycolide, Trimethylene carbonate, Ovarian pedicle, Canine, Ovariohysterectomy, Spay.

Background

The surgical procedure to desex female dogs involves ovaries removal. One intra- or postoperative complication is haemorrhage from the ovarian pedicle [1] which occurs more often in large and deep-chested breeds [2]. Moreover, duration of surgery is longer in larger dogs [3]. Furthermore, ovaries removal is a part of the surgery with intense noxious stimuli, which causes a surgical stress response [4-7]. This calls for new and improved ligation techniques.

A cable tie or tie rap, a self-locking loop, is a flexible band with a locking case at the end. Cable ties became popular in veterinary surgery in the 70s. It is suggested that duration of a bitch spay surgery can be reduced if self-locking loops are used to ligate the mesovarium [8-11]. However, traditional cable ties are made without declared good manufacturing practice (GMP). The material is nylon, a non-resorbable material which may cause chronic tissue reactions [12-15]. Therefore the use of traditional cable ties in surgery is strongly discouraged [16], as is the use of non-resorbable material for ligation purposes [17-20].

In a university research project a self-locking loop designed for surgical ligation was developed. It was first manufactured in the resorbable polymer polydioxanone [21-23] and later in a resorbable block co-polymer of glycolide (GA) and trimethylene carbonate (TMC) [24, 25] equivalent to the resorbable suture Maxon™ [26].

The aim of this study was to test the feasibility of ligating the canine ovarian pedicle with the self-locking implant made of the resorbable block co-polymer of GA and TMC and to compare its performance to that of traditional suture ligation.

Methods

Animals

A prospective clinical trial was performed to test the medical device. In total 45 privately owned or “spay-and-adopt” intact females destined for elective ovariohysterectomy and adoption were included in the study (Table 1). In 21 dogs the new resorbable implant was used to ligate of the mesovarium, and in 24 dogs traditional suture was used as control. Mean body weight \pm standard deviation of implant dogs was 10.7 ± 5.6 kg (range 3.5 – 22.0), and that of control dogs was 12.8 ± 6.4 kg, (range 4.1 – 27.0).

Before surgery all dogs were microchipped and underwent a full clinical examination, including a complete haemogram. Surgery was done on the control group first due to delayed delivery of implants.

The study protocol was approved by the local ethical committee, reference UENF-CEUA 435813.

Table 1 Description of weight and estimated age of the dogs.

Groups	Weight (kg)	Age (years)	n
Implant – LigaTie®	10.7 ± 5.6	4.1 ± 2.2	21
Control – suture ligation	12.8 ± 6.4	3.5 ± 2.1	24

Data are mean \pm SD.

Anaesthesia

Table 2 Drugs used for premedication and anaesthesia of the 45 dogs.

Drug	Indication	Dosage	Trade name	Route of administration
Acepromazine	Sedative	0.1mg/kg	^a Apromazin 0,2%	I.M.
Tramadol	Analgesic	4 mg/kg	^b Cloridrato de tramadol 50mg/ml	I.M.

Meloxicam	Analgesic	0.2 mg/kg	^c Maxicam 2%	S.C
Ketamine & Midazolam	General anaesthesia	10 mg/kg 0.5 mg/kg	^a Cetamin 10% ^b Midazolam 5mg/ml	I.V. I.V.
Lidocaine	Regional anaesthesia	5 mg/kg	^d Xylestesin 2%	Epidural

^aSyntec®; ^bHipolabor; ^cOuro Fino; ^dCristália.

Dogs were premedicated with acepromazin, tramadol and meloxicam (Table 2). Anaesthesia was induced and maintained with ketamin and midazolam, after which epidural anaesthesia was administered with lidocain.

The resorbable implant

To construct the device computer-aided design (SolidWorks®, DassaultSystèmes SolidWorks Corporation, Concord, USA) was used. The implant (LigaTie®, legal manufacturer Resorbable Devices AB, Uppsala, Sweden) consisted of a flexible band, in part perforated, and a case with a locking mechanism where the band could be introduced and pulled through (Fig. 1). One-way motion only was allowed when the locking mechanism engaged with the perforations of the flexible band, and a self-locking loop was formed. Design features for tissue engaging properties, aimed to achieve a secured tissue grip, were added to the locking case to increase friction between implant and tissue that was compressed inside loop of implant.

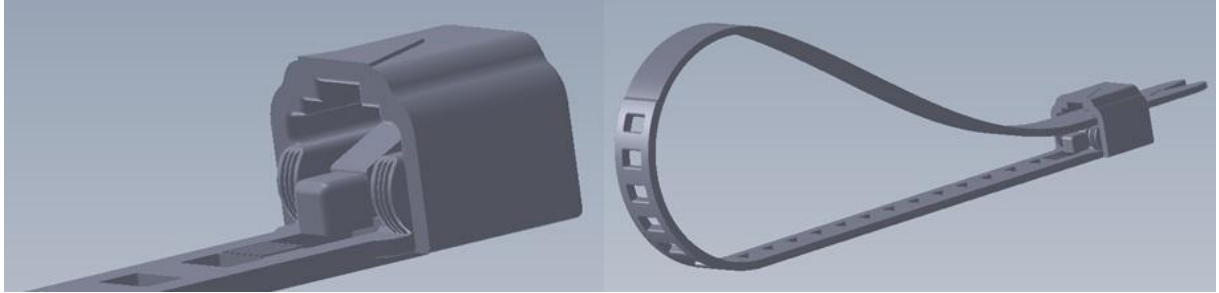


Fig. 1 The resorbable implant, LigaTie®, was constructed as a flexible band and case with a locking mechanism. Design features for tissue engaging properties were added to the locking case to increase friction between implant and tissue (left). The band was introduced into the locking case, which allowed one-way motion only when the locking mechanism engaged with the perforations, and a self-locking loop was formed (right).

Glycolide (GA) and trimethylene carbonate (TMC) were polymerized into a block copolymer. The resorbable polymer was injection moulded into LigaTie® products. The produced devices were placed in Tyvek bags, two implants per bag. The Tyvek bags were sealed in a clean room, placed in aluminium foil pouches and allowed to dry under vacuum for at least seven days. Pouches were then sealed in a moisture free environment. Implants were sterilized while inside the sealed aluminium foil pouches by using electron beam radiation at a dose of 25 kGy.

Surgery

All operations were performed by the same surgeon, with sterile assistant, and followed standard procedures, except that the device was used to ligate of the ovarian pedicles and in the control group traditional suture of the equivalent material was used (Maxon™, size 0, 3.5 metric, monofilament polyglyconate synthetic absorbable suture, manufactured by Syneture, 150 Glover Avenue, Norwalk, Connecticut 06856 USA). Total surgery time and ligation time was recorded. Any observed intraoperative or postoperative bleeding was noted in a protocol.

Dogs were placed in the Trendelenburg position and an incision was made along the midline. Uterine horns and ovaries were localized manually. A hole was made in the broad ligament close to the ovary. The flexible band was applied around the mesovarium (ovarian pedicle) and introduced into the locking case thus forming a loop. The implant's loop around the ovarian pedicle was tightened with one hand while the other hand secured the ovary. The

tissue and blood vessels within the loop were compressed. A needle holder was occasionally used for improved grip of the flexible band of the implant at final check to ensure the loop was fully tightened.

After the loop of the implant was tightened and desired compression of tissue was achieved, a pair of forceps was used in-between the implant and the ovary. The ovarian pedicle was transected distal to the implant, close to the forceps. The tissue was inspected for haemorrhage to verify haemostasis. The procedure was repeated on the opposite side.

After haemostasis was verified a second time on the ovarian pedicle, excess band extending from the locking case was removed. A short segment of the flexible band remained protruding from the locking case to allow grabbing the flexible band with a needle holder and to enable further tightening of the loop, if needed. The procedure was repeated on the opposite side.

In control dogs, a pair of haemostatic forceps was used to clamp the ovarian pedicles and make a groove. The forceps were then repositioned distally, closer to the ovary and one ligature was placed in the compressed mesovarial tissue. An extra clamp was placed on the suspensory ligament. The ovarian pedicle was cut between the ligature and the forceps. The extra clamp was removed after haemostasis was verified.

In both groups, the mesometrium was ligated after which the uterine body was ligated near the cervix with resorbable suture material (study group Vicryl, polyglactin 910, Ethicon, control group Maxon™, polyglyconate, Syneture,). An encircling ligature was placed around the cervix. If the uterine vessels were prominent they were separately ligated.

The uterus and ovaries were removed. All the transected tissue with the attached implants or traditional sutures was finally visually inspected for haemostasis. Moreover a gauze test was performed, which involved holding haemostatic forceps and applying gauze to the transected tissue. After haemostasis was verified the abdominal wall, subcutaneous tissue and skin were closed.

Post surgery and clinical follow-up

Daily control clinical examinations, *i.e.* rectal temperature, abdominal palpation and visualization of the surgical wound for dehiscence, bleeding or infection, were performed on day 1-10, until suture removal.

Comparison of groups and larger versus smaller dogs

Weight and age of dogs as well as duration of ligation and surgery were compared. Evaluation of effect of size of dogs was performed by comparing larger dogs, defined as higher or equal to the group's mean body weight, with smaller dogs. Time is given as minutes' and seconds''. The level of statistical significance was defined as $P \leq 0.05$ (Student's t-test, two-tailed distribution, two-sample unequal variance).

Definition of times

Duration of surgery was defined as from start of skin incision to last skin suture.

In the control group, the definition of time for ligation was from identification of the uterine horn (start) until transection of the second ovarian pedicle. In detail, a pair of haemostatic forceps was used to clamp the ovarian pedicles and make a groove. The ovarian pedicle was single ligated and the excess suture material was cut. A haemostatic clamp was placed between the ovary and ligature with an extra clamp on the suspensory ligament after which the ovarian pedicle was cut (stop).

In the implant group, the definition of time for ligation was from identification of the uterine horn (start) until transection of the second ovarian pedicle, haemostasis was verified and the excess band was cut (stop).

Results

The weight and age of the dogs (Table 1) did not differ between the two groups ($P = 0.25$ and $P = 0.33$, respectively). Five dogs were excluded due to abnormal haemogram (thrombocytopenia, anaemia and leukocytosis).

The ligation time of the mesovarium was significantly shortened ($P = 0.02$) using the self-locking implant versus a single encircling ligature with traditional suture ($3'28'' \pm 1'05''$ and $5'29'' \pm 3'54''$, respectively). Total duration of surgery differed between the groups ($P = 0.02$) with a shortened duration of surgery using the self-locking implant ($15'56'' \pm 2'47''$ and $20'39'' \pm 8'58''$, study group versus control group, respectively).

Among the control dogs, 10 dogs had a bodyweight higher than group's mean body weight of 12.8 kg and 14 dogs lower than the group's mean body weight. Duration of surgery for control dogs higher and lower than the group's mean body weight was $27'45'' \pm 9'36''$ versus $15'34'' \pm 3'24''$ ($P = 0.003$). The ligation time in the control dogs (suture) higher and lower than the group's mean body weight was $7'50'' \pm 5'08''$ versus $3'49'' \pm 1'13''$ ($P = 0.04$).

In the implant group, 10 dogs had bodyweight higher or equal to the group's mean body weight of 10.7 kg and 11 dogs were lower than the group's mean body weight. Duration of surgery for the dogs in the implant group higher and lower than the group's mean body weight was $17'43'' \pm 2'25''$ versus $14'20'' \pm 2'03''$ ($P = 0.003$). The ligation time in the study group higher and lower than the group's mean body weight was $4'11'' \pm 1'08''$ versus $2'49'' \pm 0'29''$ ($P = 0.004$).

In a comparison in between groups of the larger dogs, bodyweight higher or equal to the groups' mean body weights, ligation time was shorter in the implant group versus control group, ($P = 0.05$) and duration of surgery was shortened in the implant group ($P = 0.009$).

The corresponding comparison in between groups of the smaller dogs, bodyweight lower than the groups' mean body weights, ligation time was shorter in the implant group versus control group, ($P = 0.01$) whereas duration of surgery did not differ ($P = 0.27$).

Table 3 Description of time used to ligate the mesovarium and total duration of surgery.

Groups	Ligation time	Total surgery time
Study group – LigaTie®	*3'28" ± 1'05"	*15'56" ± 2'47"
Control group – suture	*5'29" ± 3'54"	*20'39" ± 8'58"

*Values differ significantly between groups. Data are mean ± SD.

No intraoperative haemorrhage was observed in the implant group. Intraoperative haemorrhage was observed once in a dog (bodyweight 21 kg) in the control group from the left ovarian pedicle. The tissue was grasped with haemostatic forceps, an additional ligature was applied and the bleeding stopped.

In one implant it was observed the band inside the locking case was tilted, outside guiding tracks on one side of the locking case, after the loop was tightened. The locking mechanism still functioned as intended, allowed one-way motion only and held the tissue firmly compressed.

No postoperative haemorrhage was observed in any of the dogs and all dogs recovered uneventfully. No wound complications were observed and the general status of dogs in all the postoperative clinical examinations was considered normal.



Fig. 2 The self-locking loop of the implant was placed around the ovarian pedicle and tightened. Tissue was transected and after haemostasis was verified the excess band was cut off. In some cases care was taken to produce a rounded cut-off end (far right).

Discussion

The results of this feasibility study suggested the implant can be used to ligate the canine mesovarium. Moreover, compared to traditional single suture ligation, time needed to ligate the ovarian pedicle and duration of surgery was significantly reduced with the implant. Time needed to ligate the ovarian pedicle and total duration of surgery was higher for larger dogs than smaller dogs.

A previous study found that duration of a bitch spay surgery was shortened by about 15 minutes when cable ties were used for ligation [10, 11]. Comparisons should be made cautiously because the previous study used cable ties in mesovarium and uterine stump. Another difference was that in the previous study an applicator was used to tighten and cut excess band of the cable ties, with additional time saved compared to manual handling. In some implant dogs of the present study, time was used to create a rounded cut-off end of the band whereas no such time was used in the control group. An applicator designed to tighten and cut the excess band of the present implant may be preferable.

Ligation time was shortened when the self-locking implant was used, compared to use of a traditional suture ligation. We chose not to clamp and compress tissue with forceps in the implant group because it could cause some haemostasis of its own and may therefore obscure an insufficient compression of the tissue. However, to compress tissue and make a groove is the recommended method of traditional ligation of the ovarian pedicle. Intraoperative haemorrhage from the mesovarium was observed in one dog in the control group. The mesovarium was re-ligated and haemostasis was confirmed. A double ligation of the ovarian pedicle is the recommended method [27, 28], and the observed intraoperative complication in the control group suggests that the advised use of double ligation of the ovarian pedicle is justified. In total 42 ovarian pedicles were ligated with the device and no haemorrhage was observed.

Previous studies reported a higher incidence of intraoperative haemorrhage and longer surgery duration in large size and deep chested dogs [2, 3]. In the present study's comparison of larger versus smaller dogs, duration of surgery and ligation times were longer in the larger dogs, in agreement with the previous studies.

The mechanical properties of the self-locking implant fulfilled the required ability to compress the tissue of the canine ovarian pedicle. In some implants marks were detected on

the surface of the flexible band, caused by the ejector mechanism of the mould at manufacturing. In one implant we observed the band inside the case was tilted outside the guiding track after the loop was tightened. An uneven surface or band outside guiding track could negatively affect a smooth passage of the flexible band through the case and make it more difficult to tighten the loop. Increased friction at tightening of loop may be misinterpreted by the surgeon as sufficient compression of tissue and therefore constitutes a risk factor. We conclude the locking mechanism functioned as intended and locked the loop tight in all cases.

There were study limitations. Surgeries were not done in a random order, *i.e.* controls were done first and implants were done second. The difference in duration of surgery and ligation times should therefore be interpreted cautiously. Follow-up was limited to a short period, 10 days. However, postoperative haemorrhage from the ovarian pedicle is usually diagnosed during the first 24 or 48 hours after surgery. In addition, the resorbable material is well investigated and its safety is clinically established.

We conclude ligation of the ovarian pedicle with the implant was feasible and saved time; however further studies involving more dogs are needed.

Competing interests

Author (OVH) is the inventor of the tested surgical implant. Company Resorbable Devices AB, Sweden, is the owner and controls the patented design and registered trademark LigaTie®. Authors N. Borg and O.V. Höglund are both part owners of the company Resorbable Devices AB.

Authors' contributions

MRMC performed the surgeries, examined study subjects and was involved in the design of the study.

ALAO was involved in the design of the study.

RMR assisted with the surgeries, examined study subjects and was involved in the design of the study.

LWMV planned and performed the anaesthesia, recorded data intraoperatively and examined study subjects.

NB was involved in development of the implant and design of the study.

OVH was involved in development of implant, design of the study and took main responsibility for drafting the manuscript.

All authors were involved in writing of the manuscript, read and approved the final manuscript.

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5. CAPÍTULO 2

Title:LIGATIE® use for ligation of the mesovarium in a bitch – case report

Matheus Roberto da Mota Costa –Médico Veterinário, Mestrando em Ciência Animal da Universidade estadual do Norte Fluminense – UENF – Campos dos Goytacazes, RJ e professor colaborador da Universidade Iguazu – UNIG - Itaperuna, RJ. E-mail: matheusmota@surgical.net

Leonardo Waldstein de Moura Vidal – Médico Veterinário, Pós-graduado em Anestesiologia Veterinária pela Pós-Anestesia Veterinária – PAV – Rio de Janeiro, RJ e Mestrando em Ciência Animal pela Universidade estadual do Norte Fluminense –UENF – Campos dos Goytacazes, RJ. E-mail: leonardowaldstein@gmail.com

Tomas Ottoni Barroso da Silva – Médico Veterinário, Pós-graduado em cardiologia veterinária pela Universidade Anhembi Morumbi – UAM – São Paulo, SP e Mestrando em Ciência Animal pela Universidade estadual do Norte Fluminense –UENF – Campos dos Goytacazes, RJ. E-mail: tomas.ottoni@gmail.com

Fernanda Antunes - Médica Veterinária, Mestre, Doutora. Professora Associada da Universidade Estadual do Norte Fluminense – UENF – Campos dos Goytacazes, RJ. E-mail: fernandaanest@uenf.br.

André Lacerda de Abreu Oliveira – Médico Veterinário, Mestre, Doutor, Pós-Doutor. Professor Associado da Universidade Estadual do Norte Fluminense – UENF – Campos dos Goytacazes, RJ. E-mail: andrevet@uenf.br

Abstract

Ligation of the mesovarium is one of the most common surgical procedures performed in small animals. The sutures are traditionally used due to its effectiveness in promoting an efficient hemostasis. The nylon cable ties also showed good efficacy for ligation of mesovarium in dogs, making it easier and reducing surgical time. However, the use of this device is related to long-term complications such as fistula formation, abscesses and granulomas. The objective of this study is to report the use of LigaTie®, a cable tie made of polyglyconate for the ligation of mesovarium on a Shih-tzubitch, 8 months old, weighing 4 kg. The LigaTie® showed high effectiveness for ligation of mesovarium in the bitch of this report. The positioning of the implant in mesovarium was simple and quick, a fact that resulted in reduced surgical time. The local inflammatory reaction observed in the presence of LigaTie® did not differ from reaction observed with traditional surgical thread when evaluated by ultrasound examination performed 30 days after surgery. Once LigaTie® is made of absorbable material, it is expected that do not present the long-term complications related to the use of nylon cable tie, since it will be absorbed.

KEYWORDS: Mesovarium; dogs; Absorbable device. Polyglyconate

1. INTRODUCTION

In veterinary medicine, ligation of the ovarian pedicle and uterine stump structures are among the most performed surgical procedures in small animals and, despite the wide range of materials used for ligation, peri and post operative bleeding are major complications reported during the ovariohysterectomy (Muraro & White, 2014).

Despite the good effectiveness of sutures to promote hemostasis of blood vessels during OVH, sought to alternatives that present better efficiency in promoting hemostasis and reduce the surgical time. One of the devices used as an alternative was the nylon cable tie (Howe, 2006). The device showed efficient hemostasis, reduced surgical time and great ease of positioning in the mesovarium during the OVH in bitches. However, significant limitations have been observed as not being a surgical implant, significant tissue reaction and formation of granulomas, the latter two being directly related with the feature of nonabsorbable material and implant design (Macedo et al., 2012).

The objective of this study is to report the use of a cable tie made of polyglyconate for ligation of the mesovarium in a bitch during ovariohysterectomy procedure.

2. CASE REPORT

Was admitted at the surgery service of the Universidade Estadual do Norte Fluminense (UENF) a shih-tzu female dog, weighting 4 kilograms. Initially, the patient was referred for presurgical evaluation. During the evaluation was obtained the history of the animal and carried out thorough physical examination. As complementary tests were performed blood count, liver and kidney serum biochemical profiles. The patient also received during the pre-surgical evaluation a microchip identification (985154000170686). There was no change in both physical examination and in the further examination to carry out anesthetic or surgical procedure. The patient was deemed fit to undergo elective ovariohysterectomy (OVH).

It was positioned a venous catheter in the right cephalic vein through which began the administration of saline 0.9%¹. Was administered acepromazine² (0.1 mg/kg) and tramadol hydrochloride³ (4 mg/kg), both intramuscularly as premedication. After observing the sedative effect the abdominal region was wide clipped. ketamine⁴ (10 mg/kg) and midazolam⁵ (0.5mg/kg), were both administered intravenously for the induction and maintenance of anesthesia. Then the patient was positioned in the prone position and held regional anesthesia with lidocaine⁶ (5 mg/kg) in the epidural space. The patient was positioned in supine position and the abdomen was prepared aseptically. By performing celiotomy was obtained access to the abdominal cavity and the right uterine horn was located manually. A hole was made in the broad ligament of the uterus near the ovary. Through this hole the flexible band of LigaTie® was positioned in the mesovarium. The end of the flexible band was positioned in the entrance of the locking mechanism being squeezed with one hand while the other was holding the ovary. After the complete closure of the flexible band (Figure 1) two hemostatic clamps were positioned between the ovarium and the implant and the ovarian pedicle sectioned between the implant and the most distal clamp (figure 2).

¹ Saline 0,9%. Lab. FreseniusKabi, Barueri, SP.

² Apromazin 0,2%. Lab. Syntec, Santana de Parnaíba, SP.

³ Tramadolhydrochlorade. Lab. Hipolabor, Belo Horizonte, MG.

⁴ Cetamin. Lab. Syntec, Santana de Parnaíba, SP.

⁵ Dormonid. Lab. Roche, São Paulo, SP.

⁶ Xylestesin. Lab. Cristália prod. Quim. Farm. LTDA - Itapira, SP.



Figure 1: Positioning of LigaTie® in the mesovarium.

The ovarian pedicle was inspected for bleeding and then performed the same procedure on the contralateral ovarian pedicle. The uterine stump was ligated near the cervix using suture made in polyglyconate (Maxon™, polyglyconate, Syneture) in a transfixing fashion. After the suture was positioned two hemostats were positioned above the site of ligation and the tissue sectioned between the ligation and the clamp. After inspection of the uterine stump for bleeding, the abdominal cavity was closed as routine.



Figure 2: Ovarian pedicle after transection.

During the first 10 days after surgery were evaluated rectal temperature, pain on abdominal palpation and surgical wound for dehiscence, bleeding and hemorrhage. The thirtieth day after surgery an ultrasound exam was performed for evaluation of the ovarian pedicles and the implant (figure 3).



Figure 3: Ultrasonographic image of the right and left ovarian pedicle 30 days after the surgery. ROP: Right ovarian pedicle; LOP: Left ovarian pedicle.

3. DISCUSSION

Despite being the surgical procedure most commonly used in surgical practice for small animals, the OSH can have significant complications. The most commonly reported in the perioperative period is bleeding from the ovarian artery (Muraro & White, 2014). It is essential to use the appropriate surgical implants, and the correct execution of ligation technique so that it has high safety and efficacy, avoiding bleeding in the peri and postoperative periods. The sutures made of absorbable material are generally used to perform ligation in mesovarium, but seeks to develop implants that allow high efficiency of ligation associated to ease of implementation and shorter surgical stress. The nylon cable ties, when used for ligation of the mesovarium allowed high efficiency associated with ease of implementation and shorter surgery (Silva et al., 2004). However observed inflammatory response was significantly higher with the use of nylon cable ties when compared to the traditional technique (Rubio et al., 2014). It was evident in this report that the use of LigaTie® promotes highly effective associated with ease of implementation and reduced surgery time hemostasis when compared to traditional OVH technique. In the ultrasound examination performed 30 days after surgery was observed mild inflammatory reaction around the implant. This reaction is common and expected after positioning an implant within the abdominal cavity. Despite the nylon cable ties present effectiveness in mesovarium ligation, these are made of non-absorbable material and due to this feature, present significant complications in the long-term, as fistula formation (Johnson-Neitman et al., 2006), granulomas, abscesses and bilateral hydronephrosis (Macedo et al., 2012; Mesquita et al., 2015).

Once LigaTie® is made of absorbable material, it is expected that do not present the long term complications related to the use of nylon cable tie, since it will be absorbed.

4. CONCLUSION

The LigaTie® was highly effective for mesovarium ligation in the bitch of this report, this was proven by the absence of bleeding during and after the procedure. The locking mechanism has allowed the movement of the flexible band in only one direction, thus preventing loosening of the bandage. The positioning of the implant in mesovarium was simple and quick, a fact that resulted in reduced surgical time. The local inflammatory reaction observed in the presence of LigaTie® did not differ from reaction observed with traditional surgical thread.

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6. CONCLUSÃO

Conclui-se que há viabilidade na ligadura do pedículo ovariano usando o LigaTie® e esta resultou na redução do tempo de ligadura e no tempo total de cirurgia.

Mais estudos envolvendo um maior número de animais e avaliação do perfil de degradação do implante são necessários.