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Research Article

The Lavender Way – Lavender Procedure, A Way to Defeat Breast Cancer Without Surgery: Chemotherapy or Radiation

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ABSTRACT

Background: Despite advances in metabolic pathways, exosomes, ct-DNA, biomarkers, and imaging technology, breast cancer is still with us. It is a global curse, with incidence set to double in the U.S. by 2030. Increasingly, researchers blame this debacle on our persistent use of unreliable preclinical testing with mouse models. Further, while basic science understanding has exploded, we know each daughter cell is genetically different, with likely increased resistance to therapy – and increased aggressiveness. Nonetheless, our current approach requires killing every one of these daughters to the last. The authors have devised a new game plan; the new goal is to kill the very first cells, not the last ones. This can be implemented globally – with dramatic cost reduction, and more lives saved while leaving the breast intact.

Methods: The authors have created The Lavender Way, which employs multiple non-radiation diagnostic modalities. This allows us to predict within ten years in a person's lifetime when breast cancer will likely manifest. Then imaging is accelerated with modified military Infrared, ultrasound, and others to locate ultra-small breast cancers (5-8mm). Tumor analysis can determine each tumor's aggressiveness. Via a 20-minute office procedure under local anaesthesia (i.e., Cryoablation, aka The Lavender Procedure), the tumor can be killed with the patients resuming normal activity immediately. It is both a dramatic change in treatment and, just as significant, a dramatic change in lifting the psychological burden of this dreaded disease.

Results: Group I: Ideal Patients, Group II: Less than Ideal, Group III: Strictly Palliative. All in Group I are alive after seven years except one. That one died of a fall, cancer-free, and one is alive with a local recurrence successfully treated with repeat cryoablation. Group II had one local recurrence, and one had a second primary tumor in a different location in the breast. Group III refused any other treatment and had metastatic disease. They were treated to prevent tumors from eroding through the skin. Most have died. The Lavender Way paves the way for The Lavender Procedure.

Conclusion: Ultra-small breast cancers with optimal bio-markers are ideal candidates for The Lavender Procedure (i.e., Cryoablation). All patients resumed normal activity immediately – without sutures. All patients in Group I and II patients have avoided surgery, chemotherapy, and radiation.

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Introduction

Ever since man became interested in aiding his fellow man with any medical treatment, the breast, which has always been a source of

esteemed beauty, sexual desire, and the epitome of femininity, has been subjected to horrendous surgical assaults throughout millennia (Figure 1). From the Edwin Smith Papyrus to Galen to Virchow to Halstead and Bernard Fisher (initiating clinical trials), we have seen an evolution of

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minimizing the once heralded radical surgery [1]. This move from radical surgery to lumpectomy and sentinel lymph node biopsy (over the past 30 years) is being supplanted now with so-called ‘Oncoplastic Surgery,’ which is nothing more than an attempt by general surgeons to invade the realm of the plastic surgeon; all the while heralding the cause as cosmetic. The United States alone has spent hundreds of millions on clinical trials that verified lumpectomy (in most cases) was the treatment of choice, less disfiguring. It took over twenty years for lumpectomy to become ‘standard of care’, and now it is being systematically attacked. The notion that a surgeon can go to a ‘weekend’ course on ‘oncoplastic’ technique and become competent that effectively replaces years of plastic surgery residency is preposterous.



Figure 1: This photo depicts the aggressive surgery of the 1970’s compared to Lavender on the right just about two minutes after the procedure with a dab of antibiotic ointment, no suturing ever.

A naive public and frightened women who have grown up with the notion to ‘Just get it out of me,’ have permitted this nonsense to be perpetuated thus reverting back to “getting it all”, accompanied with the equally preposterous assurance that the breast will attain a cosmetic result second to none. Almost every advance in less disfiguring treatment has been met with opposition from a hierarchy of self-proclaimed key opinion leaders. Evidence-based medicine, which has come into vogue ushered in by an increasing number of functionaries, has eviscerated the ‘art of medicine.’ Doctors under the constant threat of litigation or an aggressive non-understanding medical board or a restrictive H.M.O. are afraid to step out of the safe harbor of ‘standard of care.’ While it can be argued that evidence-based medicine has its place in documenting progress for posterity, it cannot be relied on to provide optimal care to an individual patient. Years of experience interacting with patients hone one’s ability to treat cancer, adding to one’s expertise as decades go by. Dogma and tradition make it almost impossible for radical change to free us from “the confident complacency of assumed righteousness in the way things are done” [2]. Having been trained by aggressive surgeons (whose motto was, ‘For them it is unresectable’), we participated in the holocaust on women that dictated radical disfiguring surgery was the key in the late 1970s. Embracing lumpectomy following Umberto Veronesi’s seminal paper in 1979 led to further reductions in the aggressive approach, including embracing Accelerated Partial Breast Radiation (twice daily for five days), (Figure 2), which partially supplanted the five days a week for six weeks with a booster at the end, namely external beam radiation.

Further refinements in radiation, i.e., IORT (Intraoperative radiation), led to a breakthrough to minimize treatment (Cryoablation) and refinements in the basic understanding of the genome and infrared technology as well as other non-radiation imaging devices. Technology has caught up to breast cancer if one bothers to look. This is a core problem as hardly a few doctors appear interested. Instead of chasing the

last cancer cell to kill it, we embraced the journey of finding the first cell as close as possible, thus ushering the age of The Lavender Way/Procedure. Cancer, in its final display of authority over the body, “crushes hope, leaving a wasteland of grief, depression, despair and a sense of unending futility” [2]. What if it were possible to obviate everything breast cancer has wrought on us for millennia? What if breast cancer treatment could be taken not only out of the operating theatre but out of the system altogether at the cost of a few hundred dollars (depending on how much one wanted to save), save lives, and make it available to virtually every woman globally?



Figure 2: This photo depicts APBR with a lumpectomy and Sentinel node incision.

Methods

I Infrared

Multiple non-radiation modalities besides mammography are used to optimize our chances of finding ultra-small tumors (5-8mm). Those include modified military Infrared, ultrasound, Halo, and Sure Touch devices. The I.R. technology used is not that of the 1970s, where, in the past, Infrared obtained a bad reputation. It was classified military until about 2002 when then-President Bush declassified it. The patient is seated disrobed on top, 4ft from the cooling device, which houses an 8000 BTU air conditioner. No hand ice cooling is necessary. The ambient temperature in the room is maintained at 73 degrees. First-degree mirrors are attached to the chair and placed to image the lateral aspects of each breast. The test runs for four minutes (including 3000 images), and results are available immediately, including neural network (running the patient’s heat signature by known cancer cases). As time passes and more cancer heat signatures are added, the result becomes that much more accurate. In the first 500 patients, the false-negative rate was 0.4%. The smallest cancer found was 4mm.

The Infrared employed is not the technology of the 1970s, but rather modified military digital infrared coupled with immediate computer readout of results and analysis via a neural network (artificial intelligence). The unit is called Sentinel Breast Scan, developed by First Sense Medical. What is infrared? Infrared is part of the electromagnetic spectrum lying between visible and microwave segments of the spectrum. An infrared imaging camera observes, and measures thermal energy emitted from an object. The higher the object’s temperature, the greater the I.R. energy emitted. The infrared camera is a non-contact device that detects infrared energy and converts it into an electronic signal that is then processed to produce a thermal image on a video

monitor. It also performs temperature calculations. Recent innovations in detector technology have made its use in breast imaging much more accurate. A microbolometer is used as a detector in infrared cameras. Emitted infrared energy from an object with a wavelength from 8 to 13 um strikes the detector, heating it, and changing its electric resistance. This resistance change is measured and proceeds into temperature, which can be used to create an image on the video monitor.

The microbolometer used in the FLIR A 40 is an uncooled thermal sensor. Simply put, the military uses advanced infrared technology because it works. The military uses infrared from sniper scopes to cameras onboard the Predator to visible light video tracking systems such as THEL (Tactical High Energy Laser). By using Infrared as an adjunct, the tracked target's imaging is improved under no-light conditions or heavy cloud cover. Thus, the target's bearing, range, and elevations can be continuously updated. It is called Range Phenomenology. Modern uncooled detectors all use sensors that work by the change of resistance, voltage, or current when heated by infrared radiation.

A possible sensor assembly uses an integrated circuit with barium strontium titanate, bump-bonded polyimide in a thermally insulated connection. The FLIR A40 detector is a focal plane array, an uncooled microbolometer with 320,240 pixels. The neural network should be continuously updated. It currently uses a collection of infrared reports integrated with pathology reports and programmed into the computer. The military has a name for objects on the ground sensed by Infrared from the air: "heat signature." So too, do cancers leave a "heat signature." The neural network is designed to learn and then becomes more accurate as experience develops. The current camera has the capability of detecting heat coming from developing cancer of 1.5 mm. It also works independently of angiogenesis and has detected small (2 mm) clusters of evolving benign calcifications (Figures 3-10). Halo is a liquid biopsy device that potentially alerts the doctor to nascent cancers about 2mm or less. Sure-Touch is a pressure sensing device able to identify single and multiple targets, hard and soft at 5mm (Figure 11).



Figure 4: This photo depicts the chair with first-degree mirrors.

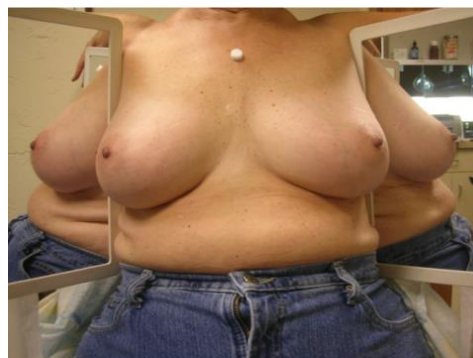


Figure 5: This photo depicts a patient in the chair with mirrors reflecting the lateral aspect of each breast.



Figure 3: This photo depicts the infrared machine set up.

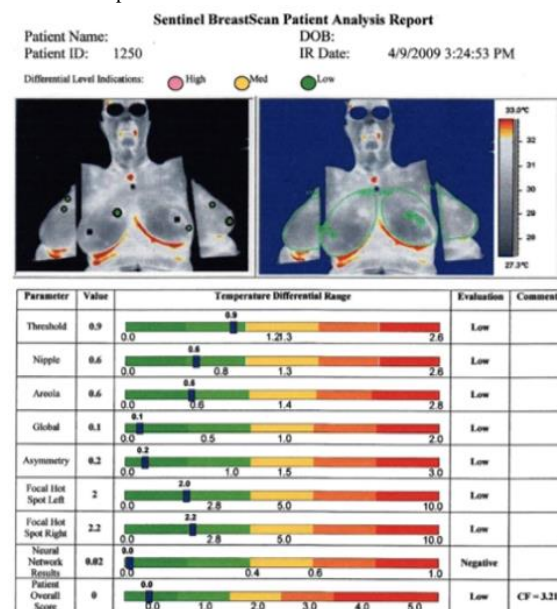


Figure 6: This is the report generated immediately. It has multiple readings, including threshold both depicted above left and below on the coloured bars showing temperature differential. The threshold above left shows the most reluctant tissue to cool down; it is either the small or big circle and either green, yellow or pink. The photo above right displays lines drawn by the operator to direct the computer where to analyse. The locations and which breast are seen on the left, followed by the temperature differential; then evaluation and lastly the comment section

will identify right or left breast U.O.Q. etc. It is better to be in the green. The evaluation section is either low or high and the neural network is either positive or negative (indicating it has seen this heat pattern before and likely cancer). The comment section is critical. If there is an indication of what breast and where in the comment section, it usually means the sensors have identified an area that demands attention. Lastly, while this report is negative (83.8% were), it does show a cancer (not in the breast). Can you find it? It's a basal cell carcinoma in the neck. We call it the 'Ruby Sign.'

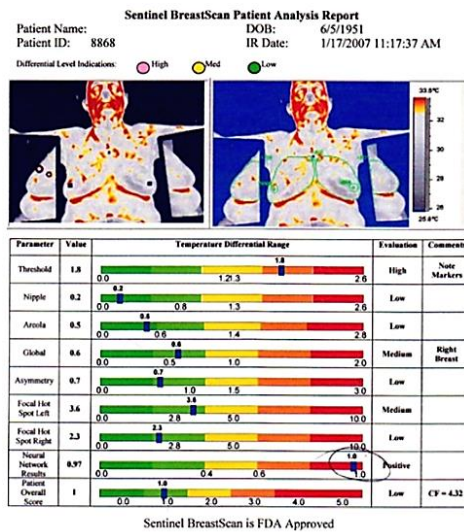


Figure 7: This report depicts a patient with probable cancer in the right breast in the U.O.Q., can you tell why? Look at the neural network and threshold image.

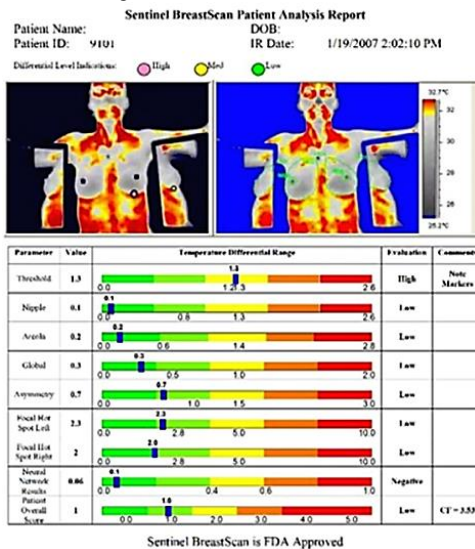


Figure 8: This report shows a target in the left breast at six o'clock. However, unlike the mammogram which called it suspicious for cancer, it is telling us the lesion is benign and so it was on biopsy. The false negative rate for mammography in our series was 24%. The lesion was actually just about a 3mm focus of evolving calcifications. This report also demonstrates that I.R. can pick up targets without neo-vascularization. Reports such as this also demonstrate that combined with other modalities, especially genetics risk, we can potentially limit breast biopsies (of which there are over 700,000 in the U.S. annually and about 80% are benign).

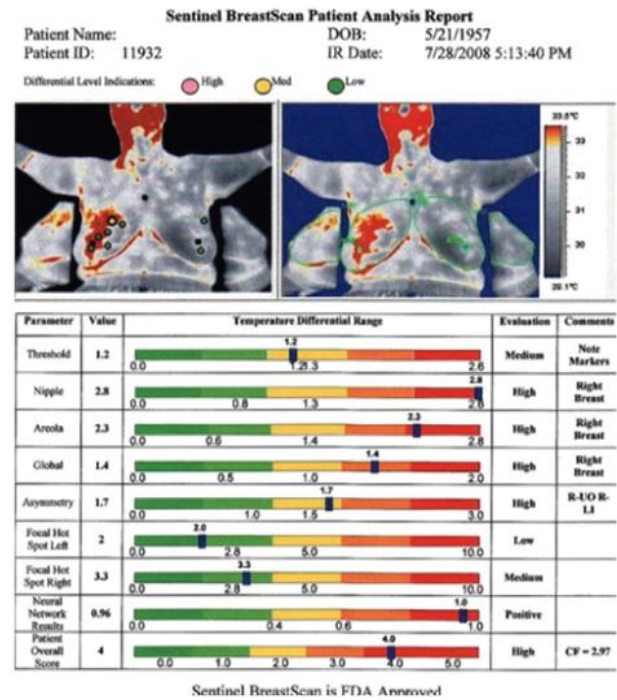


Figure 9: This report demonstrates a large right breast cancer with multiple findings.

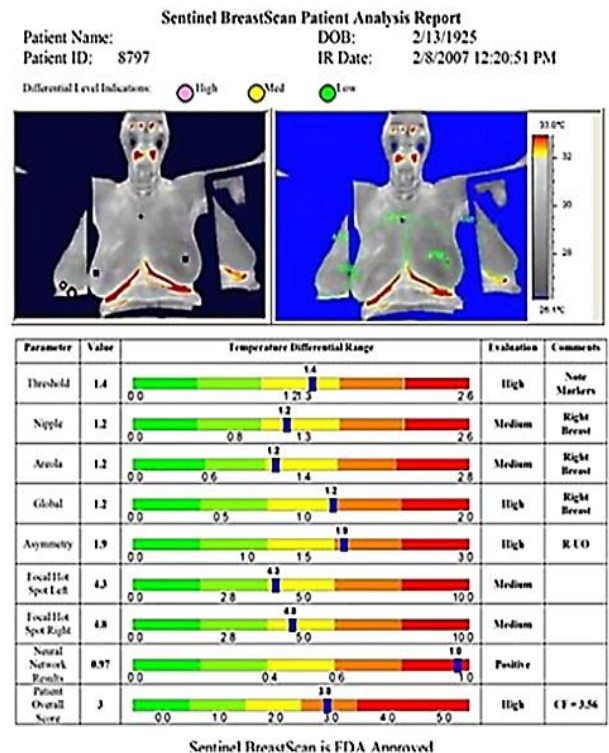


Figure 10: This report demonstrates cancer in the right breast, or does it? Look at the images and read the graph, evaluation and comment sections. A work up of the breast, including M.R.I. failed to demonstrate a cancer in the right breast. Where could the cancer be? It was in the right upper lobe of the lung.

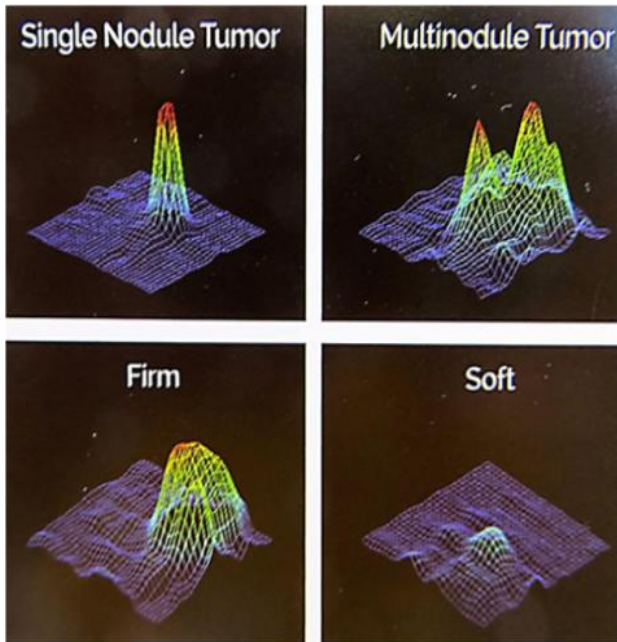


Figure 11: This is a Sure-Touch representation of typical targets identified using this pressure sensing device. It can identify targets as small as 5mm. The patient (once instructed) could do this at home to complement self-breast exam and the report sent into the cloud.

II Why is it Named Lavender?

One of the first patients to undergo Cryoablation (with implants) was hungry right after, and she suggested we walk across the street to Lavender Bistro (a high-end French/American restaurant in La Quinta, CA). Within twenty minutes after the procedure, she was dining on lobster salad and, yes, toasting with a sip of chardonnay, like the procedure never happened. She is now in her seven and a half years cancer-free, no surgery, chemo, or radiation.

III What is the Lavender Way?

Simply put, it starts with a healthy 20 something who undergoes genetic risk testing, not BRCA testing, which is only suitable for about 10 percent of breast cancer patients. It is a saliva test that singles out age-specific SNPs (single nucleotide polymorphisms), so we can predict not only lifetime risk but when that risk is likely to manifest within ten years. In most cases, this gives us decades to alter lifestyle changes and active prevention with Nolvadex or Raloxifene when a patient hits menopause. This genetic information is used to decide what imaging should be done and how often, independent of any guidelines, genuinely personalized care. Then as the time to the theorized appearance of the cancer approaches, imaging is accelerated since none of these diagnostic modality's harbors radiation. Mammography and M.R.I. are included on an as-needed basis. This approach may have saved Miss Venezuela, who died of metastatic breast cancer at age 26. She brings home the point. Yes, by herself, it is just an anecdotal case, but be assured it was not anecdotal to her family. Cancer cuts deep and is a very sobering personal experience for each person. Our task is to unload that burden.

It is not just that. Lavender is a sanctuary dedicated to educating young and older women on the journey of life's health problems and how to

avoid their impact. It is giving them street smarts. The same doctor sees patients for decades (sans E.M.R.), so a real understanding of each patient's needs and real communication takes place in a trusting atmosphere. Each patient knows what steps are being taken to diagnose and prevent breast cancer. She knows as well, if those steps are followed if cancer does ever arise, she should be a candidate for The Lavender Procedure, meaning Cryoablation, hopefully being able to avoid any surgery, chemotherapy or radiation.

This situation calls for an entirely different approach than instituting a nationwide breast screening programme and hoping women flock in. Family physicians acting as gatekeepers and some self-appointed key opinion makers dictate thru some 'national guidelines' when and how often a woman undergoes what type of imaging. This approach must stop. We must abandon the one size fits all and replace it with a truly personalized caring environment. There are increasing numbers of women deciding to avoid mammography altogether for various reasons, including the fear of radiation. The Lavender Way would be effective here with genetic testing and the use of multiple non-radiation modalities. Otherwise, this burgeoning population of women would just come in with advanced tumors. The treating breast doctor must be beyond fluent in reading mammograms (actually viewing each one along with the patient), trained to be multi-talented and able to act (if necessary) the same day, i.e., ultrasound-guided core biopsy. The sine qua non of Lavender is that the patient leaves the center armed with the knowledge that generally would sometimes take weeks to learn and what will be done about it. That is, the very same doctor she has seen for sometimes decades can carry out treatment after all options and second opinions are explored.

The current system in the U.S. is not geared to finding ultra-small cancers, and major cancer centers must deal with whatever palpable cancer walks through the door. It is their fatal flaw. This perpetuates the "slash-poison-burn" approach as Dr. Raza so eloquently puts it. Another sine qua non is no waiting. If the patient needs to be seen that day, she is. No gatekeeper stands in the way of alleviating the oppressing distress that finding a 'lump' brings. The Lavender Way paves the way for The Lavender Procedure.

IV What is the Lavender Procedure?

Simply put, it kills a DCIS or invasive breast cancer in the office in about 20 minutes under local anaesthesia using a liquid nitrogen emitting probe to engulf the tumor under real-time ultrasound (Figures 12-17). In a play on words like the sign that read, "All Ye who enter here abandon all hope," to understand the Lavender method, the sign needs to read, "All Ye who enter here abandon all previous dogma on breast cancer treatment." Starting with a blank sheet of paper was/is the order of the day. A sterling example is that for decades, surgeons, pathologists, oncologists, and radiation therapists have fretted about obtaining 'clear margins' and exactly what that constitutes. In Lavender, the tumor is never removed, so margins never come into play in the traditional sense. The operating surgeon knows the genetic potential, family history, markers, and size of the tumor to ensure an adequate P.K.Z. (peripheral kill zone) which can be altered at will to engulf the tumor and surrounding tissue. This process is easily seen on ultrasound.

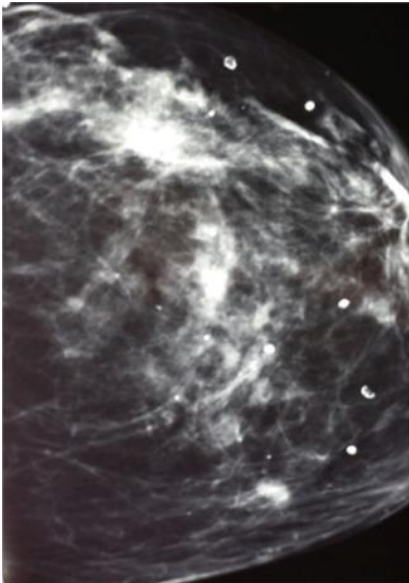


Figure 12: This mammogram shows a CC view of the left breast and a cancer medial (see arrow). This patient is significant in that she first developed breast cancer in her early thirties and lumpectomy and external beam were performed (architectural distortion laterally). After about 14 years, she had a local recurrence at the original site. It was treated with re-lumpectomy and APBR, not mastectomy, as a standard of care would dictate. She went another 15 years and then had a second primary in the same breast (three cancers in all), well medial from the original site. The patient was adamant in trying to preserve her breast. Five years ago, she underwent The Lavender Procedure, i.e., Cryoablation and has been cancer-free, breast intact and on Nolvadex for over five years.

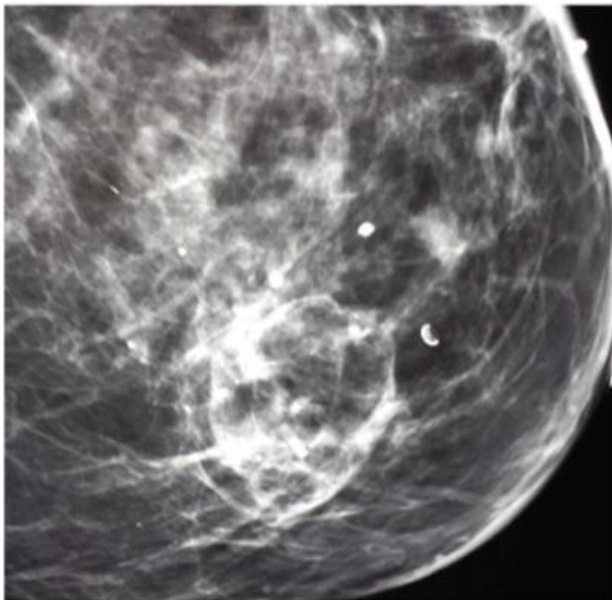


Figure 13: This is her mammogram five years out with the typical residual 'cryo halo' with no evidence of cancer. See arrow. It remains clinically palpable but only about 5mm. The original lateral position has been submitted to two core biopsies over the years also without a recurrence.



Figure 14: This series of ultrasounds depicts the tumor below; the middle image is the cryoprobe skewering the tumor and the top is the growing freeze ball encompassing the tumor and P.K.Z. (peripheral kill zone) well beyond the tumor margin. The operator controls the size and location of the freeze ball so excision of the tumor with verification of negative margins is not necessary. The total kill is confirmed on core biopsy two months post procedure.

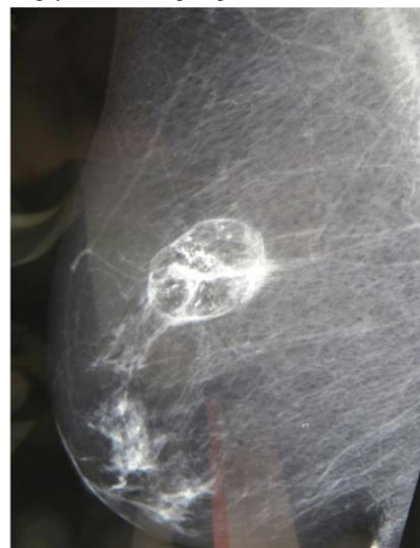


Figure 15: This mammogram depicts a typical freeze ball years after the procedure. Most patients end up with a small (few millimeter) nodule as a remnant of the original freeze ball.

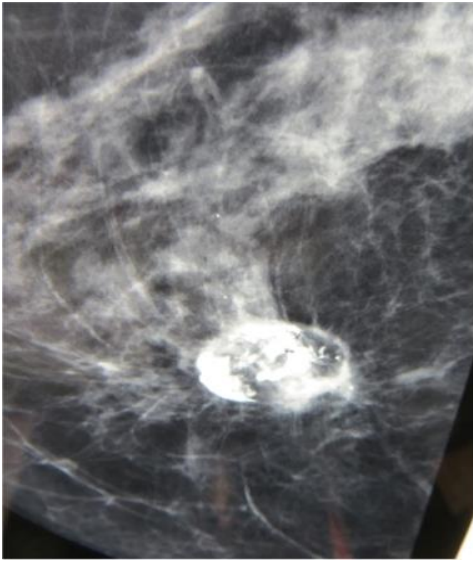


Figure 16: This mammogram depicts a more calcified freeze ball which often happens but is usually small.



Figure 17: This ultrasound image depicts the typical liquefaction following Cryoablation and it usually stays like this for about 3 years on ultrasound.

V Advantages of Lavender

- i. It is a 20-minute in-office procedure outside the OR and system, hopefully avoiding surgery, chemotherapy, and radiation.
- ii. Patients resume normal activity immediately, with no downtime.
- iii. No suturing is necessary.
- iv. Lavender saves on environmental concerns and time.
- v. Lavender does not preclude either chemotherapy (pre or post-therapy) or radiation in selected cases.
- vi. Patients are awake throughout the entire process. Once the probe is placed, a significant other may enter the room to hold the patient's hand or just observe. It dramatically changes the frightening experience (waiting in the hospital) to an almost "high," watching the tumor being engulfed by the freeze ball. It brings needed understanding.
- vii. There is no general anaesthesia.
- viii. The aim is no axillary dissection (depending on ultrasound, genetics, and markers).
- ix. There is a low chance of infection.
- x. There is a dramatic reduction in cost, the entire process from diagnosis to treatment costing a few hundred dollars to a few thousand (depending on how much is to be saved) vs. about \$125,000 for an average breast cancer case from diagnosis to treatment in the U.S. There is the potential to save over 10 billion dollars annually.
- xi. It would be available to the entire population, thereby leveling the playing field for the underserved.
- xii. Any doctor in a country where surgeons or radiologists are not plentiful can be trained.
- xiii. In countries with remote populations, i.e., Africa, the entire process could be achieved on an 18 wheeler offering (if need be) diagnosis and treatment in one day.
- xiv. Because The Lavender Way is efficient at finding ultra-small tumors, most will be hormone positive and susceptible to an anti-estrogen of choice to complement the procedure. While tumors will generally become more aggressive as they grow, finding an ultra-small tumor usually means less aggression and positive hormone receptors.
- xv. There is increasing evidence that upon resorption of the dead tumor cells, the patient's immune system responds in producing specific antibodies against the tumor. Long-term analysis of this phenomenon needs follow-up for any recurrence prevention, e.g., The Abscopal Effect.
- xvi. The Lavender Procedure can be repeated without sacrificing the breast.
- xvii. Cost in 3rd world countries could be drastically reduced, allowing treatment of all women.
- xviii. Multiple tumors in one breast can be treated the same day. We call it the "snowman" since one freeze ball will be on top of another. This option is limited, and perhaps one additional tumor close by is acceptable, not scattered multiple tumors.
- xix. Mammography/ultrasound and core biopsy are performed two months post Lavender to ensure total kill of the tumor. Should any residual tumor be present, the patient has the option of a repeat Lavender or moving on to more standard care. This option is not open if mastectomy has been performed. Essentially, no time is lost as the patient is usually on anti-estrogen therapy.
- xx. Lavender can be performed on patients with breast implants.
- xxi. Lavender can be performed on elderly patients so as not to impede their quality of life.
- xxii. Instead of the patient's relentless depressing mood with traditional therapy, the extremely positive outlook expressed by the patient and their families is second to none.
- xxiii. Last but not least, it is virtually impossible to tell the breast was ever touched. We have seen the long-term positive emotional and psychological implications for the patient, partner, and family.

VI Disadvantages of Lavender

- i. The doctor must be trained/skilled in real-time ultrasound probe insertion.

- ii. In most cases, there would be no “in hospital” code team should the patient arrest.
- iii. This is not for every patient, especially larger tumors, 2cm and above.
- iv. Potential skin damage because of contact with the nitrogen freeze ball is avoided with an infusion of saline acting as a buffer and utilizing warm saline compresses to help protect the skin.
- v. As in lumpectomy, it may require a second procedure.
- vi. There is possible pain on insertion of the probe, which is generally well controlled with local anaesthesia.
- vii. Potential for infection; however, none so far going into the 6th year.
- viii. Most patients end up with a few millimeters residual freeze ball, at times palpable.
- ix. In 2020 this procedure is currently not covered by insurance.

Patient Selection

Since this is a fledging endeavor for most doctors, limiting patients with tumors 1cm or less and easily seen on ultrasound should portend success. However, before attempting a live case (as the patient and family are present), practicing skewering an olive or the like with a probe under ultrasound guidance is recommended. A turkey breast serves the purpose. The nodal situation could be dealt by performing a needle biopsy of an axillary node via ultrasound, if possible. If tumor analysis dictates a less aggressive tumor (which is what Lavender Way portends), e.g., low Ki-67 and clinically negative nodes, and benign appearance on

ultrasound, we have avoided any node surgery, including Sentinel. Thus far, there have been no positive axillary lymph nodes years later. Generally, most of these smaller tumors will still be hormone-positive, and patients started on an anti-estrogen of choice depending on age. An ultrasound technician may assist until expertise is developed.

Informed Consent

A thorough informed consent should extol the virtues of each option from mastectomy to Cryoablation. The patient should not be ‘talked into’ Cryoablation but embrace it after considering all options with their pros and cons.

Results

Between January 2014 and August 2016, I have performed 25 procedures on 21 patients. One patient had multiple synchronous bilateral cancers and refused any treatment but Cryoablation. Because of her and others refusing any other treatment, we performed Lavender on larger tumors, up to 3.5cm. Most of those patients ultimately died of metastatic disease. We have divided the patients into three groups. Group I are ideal patients that we felt disease in the breast could be controlled. We do not use the word cure. Group II patients had less than desirable targets, i.e., DCIS (no precise solid mass on ultrasound) and Group III are patients who refused traditional treatment with larger tumors where we knowingly had no real chance for control except for preventing skin invasion and considered these palliative procedures. The legend for (Table 1) follows.

Table 1: Kind of patients we performed the Lavender Procedure on, from primary breast cancers to local recurrences and some larger tumors.

	Group I (11 patients)	Group II (4 patients)	Group III (6 patients)
Ages	43-86	65-75	38-81
Tumors	5mm-1.1cm	Tis (DCIS) - 8mm	Tis (prior lumpectomy) - 3.5cm
Breast	UOQ - 6, UIQ - 2, LIQ - 2, LOQ - 1	UOQ - 3, LIQ - 1	UOQ - 5, LOQ - 1
Markers	ER+ 8, PR+ 8, Her2- neg (7)	ER+ 4, PR+ 3, Her2+	ER+ 3, PR+ 1, Her2+1
Ki-67	mostly very low	N/A	no data
Nodes	all clinically and U/S benign	all clinically neg/ U/S benign	all palpable nodes
Freeze ball	4-5cm	3cm	5cm
Saline	7 yes, 4 no	2 yes, 2 no	all
Anti-estrogen	most all	most all	mostly refused
Sequence	usually 6-10-6	usually 6-10-6, one 4-10-4 (recurrence)	multiple attempts
Old Local Recurrence	2 (FROM IDC 2003 & 2007)	2 one DCIS and another second primary	1
Anaesthesia	0.25% Marcaine without epi uniformly		
EBL	Minimal	Minimal	Minimal
Complications	0	0	0
Alive cancer-free	10	3	1
Deaths	1 from fall not breast cancer	1 from primary lung not breast	One died we can verify as some in Group III were from foreign countries where we lost contact.

The authors understand this is a small patient population and no real statistics can be rendered. However, how many times does one need to jump out of an airplane with and without a parachute to know that jumping out with a parachute is far superior and no multicenter clinical trial is needed to prove it. Having been trained in the radical surgery era, from our first case we knew this methodology was a real game changer. Every woman is not a statistic but a valued human life. Our endeavors are meant to show the way to others who will venture into cryoablation, aka The Lavender Way/Procedure. Find it early, kill it early. If you or your country need help, contact us.

Ages – refers to the age range of the patients
 Tumors – refers to tumor size at the time of Lavender

Breast – refers to the location on the tumors by quadrant
 Markers – refers to standard tumor markers such as ER/PR

Ki-67 – refers to the proliferation rate of the tumors. Generally, these ultra-small cancers have a lower proliferation rate.

Nodes – refers to whether the lymph nodes were clinically or by ultrasound positive/negative

Freeze ball – refers to the actual size of the liquid nitrogen freeze ball which the operator can adjust (smaller or larger) according to how extensive the kill zone should be. For example, a small fibroadenoma freeze ball should encompass the fibroadenoma. But a freeze ball to kill a 1.5cm cancer (depending on the aggressiveness of the tumor) might be 5cm in total. Since in cryoablation the tumor is not excised, the operator must take into account what would be under normal tumor excision a ‘rim’ of normal tissue. In cryoablation this is called the ‘PKZ,’ the peripheral kill zone. This is easily seen during the procedure with real time ultrasound.

Saline – refers to whether or not saline was injected at the time of the procedure to prevent the freeze ball from touching the skin. Liquid nitrogen is about -180C or almost -300F. Thus, the skin would be damaged if the freeze ball touched it. There are three ways to protect the skin. First, is the use of injected saline under ultrasound guidance. Saline acts as a buffer. Two – the operator can push the tumor down away from the skin using the handle of the probe. Three – continued use of warm compresses if needed has protected the skin.

Anti-estrogen – refers to any of the anti-estrogen medication like Tamoxifen, Femara, or Arimidex. Usually, smaller cancers are more likely to be hormone positive and thus the addition of an anti-estrogen helps prevent any local recurrence just as in standard excision.

Sequence – refers to the programme dialed into the cryoablation machine by the operator based of how large the desired freeze ball should be. The longer the sequence, the larger the freeze ball. For instance, a 6-10-6 kill means there is an initial 6-minute cycle of the developing freeze ball followed by a 10-minute thawing (this changes the extracellular matrix immediately around the tumor enabling a more complete kill). Finally, another freezing 6-minute kill. The sequence usually produces about 5cm freeze ball. A ‘pearl’ – always give the tumor the benefit of the doubt and don’t skimp on the freeze ball size, it almost always gets absorbed over time.

Old Local Recurrence – refers to the number of patients where mastectomy was spared because of a history of breast cancer lumpectomy followed by radiation, where standard-of-care would dictate mastectomy for a local recurrence, as it is unlikely the breast would be radiated again using the same external beam. This mastectomy dogma can be retired. Cryoablation (aka The Lavender Procedure) has been used on multiple patients with a local recurrence without a recurrence.

Anaesthesia – refers to the choice of local anesthetic by the operator. All the patients presented herein were treated with 0.25% Marcaine without epinephrine. Usually, it was found that 15ccs of Marcaine was more than adequate for prevent ANY discomfort during the procedure. In addition, use Ethyl Chloride as a spray then make a wheal on the skin before the stab wound using Marcaine in a insulin syringe.

EBL – refers to the estimated blood loss which was in all cases very minimal.

Complications – none were observed during all these cases and every patient resumed normal activity immediately.

Alive cancer free – refers to the patients on years of follow up that are not only alive but cancer free.

Deaths – refers to deaths of patients that are recorded, one from a fall cancer free and another that was years out breast cancer free but

developed a primary lung cancer. This patient caused us to consider surveillance with chest-x-rays.

Equipment List

- i. A table to place the patient in semi-Fowler’s position
- ii. Sterile half sheet and scissors to cut an appropriate hole for the breast
- iii. 2 pillows (one for the patient’s head and another to prop up the patient’s side)
- iv. Mobile tray with a sterile cover
- v. Local anaesthesia of choice (0.25% Marcaine without epinephrine)
- vi. Liquid nitrogen (ensure enough for scheduled cases)
- vii. Tuberculin syringe (to create a skin wheal)
- viii. Five loaded 20cc syringes with sterile saline with 25ga. needle (for buffer)
- ix. 4x4 gauze, and 2-inch Transpore tape to prop up the breast as needed
- x. Betadine
- xi. 11 blade knives with Ethyl Chloride to spray skin before local anaesthesia is applied.
- xii. Ultrasound machine – cryoablation unit
- xiii. Sterile water (for probe testing)
- xiv. 2 probes (should the primary probe fail, other held in abeyance)
- xv. Signed consent for procedure and filming, including whether face should be blurred.
- xvi. Smelling salts in case of a vaso-vagal reaction
- xvii. Medium hot water soaked 4x4s for warm compress (changes as needed to protect skin)
- xviii. Sterile gloves
- xix. Antibiotic ointment and 2x2 gauze with Transpore tape to cover probe entrance site
- xx. Camera
- xxi. Dedicated personnel to provide warm compresses and change Dewar

Follow Up List

- i. A phone call to the patient the day after, for status check
- ii. The patient is notified (again) to contact the office for any problems
- iii. Office visit one week later for a recheck and perform ultrasound
- iv. Mammogram/ultrasound with core biopsy two months later to ensure a total kill
- v. Mammogram every six months for three years/ultrasound every six months for five years, then yearly
- vi. Document patient taking anti-estrogen
- vii. Continued data collection and publication of results are critical

Discussion

If breast cancer were as lethal as a bite from a Black Mamba (a highly poisonous snake), then patients in Group I should all have died from metastatic breast cancer. However, going into the 7th year, they have not. Perhaps Lavender has shown another way to diagnose and manage breast cancer that can put breast cancer in the history books. Countries must first decide just how important women are and institute an environment

like Lavender to change the paradigm. Most in Group I had invasive breast cancer, and some would say treated outside of 'standard of care', yet (all technology is F.D.A. cleared) they are all alive except one (from the fall) and cancer-free into the 5th and some beyond 7 years. As would be expected, these very early cancers are usually hormone positive and lower Ki-67, thus permitting no axillary dissection. Thus far, there is no positive nodal involvement. The procedure can be performed on patients with implants and is an ideal alternative for elderly patients with limited mobility, which might be exacerbated with axillary dissection and subsequent nerve damage. The cosmetic result is indeed second to none in preserving a woman's natural breast. Since only two months go by after Lavender (with the patient usually on an anti-estrogen) when mammography and biopsy are done, essentially no valuable time is lost if a residual tumor is found to proceed with another attempt or move to lumpectomy. Lavender has been successfully used on local recurrences where tradition dictates mastectomy. In each case, the breast was able to be preserved. One patient has had three cancers in one breast stemming from cancer in her early 30s, where lumpectomy and external radiation were employed. This was followed by a local recurrence 14 years later, and APBR (Accelerated Partial Breast Radiation) was employed and yet another cancer, 15 years later, in another part of the breast and Lavender was employed.

This was well outside of 'standard of care;' however, she is now more than seven years out and thus far cancer-free with an intact body. Patients (where possible) have been followed for a minimum of five years and some more than 7.5 years, including those treated with a local recurrence. Another critical issue is implementing Lavender Centers nationally would help obviate the known discrepancy of decreased survival and developing more aggressive tumors earlier in life between African-American women and all other races. Lavender would level the playing field overnight. The key to this entire endeavor is the foreknowledge of when the cancer is most likely to strike and to accelerate the non-radiation modalities to find these nascent tumors amenable to Lavender, thus obviating surgery, chemotherapy, and radiation. To ensure success at the outset, one should limit their foray into Lavender with very easily and sharply defined targets on ultrasound. Group II patients are examples of less-than-ideal targets with less-than-ideal results. Experience will dictate the limits of Lavender. We were self-taught as there was no one six years ago providing instruction. We have learned both the limits and the unlimited potential of Lavender. Group III was solely palliative in nature to prevent these tumors from eroding the skin.

The other side of the coin is the horrendous psychological battles that rage relentlessly in a patient just diagnosed with breast cancer. As a patient recently wrote, "It's like staring into an abyss without means of comfort thinking the worst, leaving your children and family behind." Not so with Lavender. The psychological turnaround is dramatic. There is no downtime, and bodies are intact (unscathed from side effects of surgery, chemotherapy, and radiation). This positive turnaround is seen, especially with the patient and her family being able to watch the entire procedure. They can watch the cancer being killed right before their eyes. It is dramatically euphoric. Lifting this burden from women that have haunted them for many millennia is finally within reach. The status quo needs to be challenged.

The Abscopal Effect – While complicated, a simple explanation is that under certain conditions, a combination of immunotherapy with Cryoablation not only kills cells locally but may effectively kill cancer cells in the periphery. With the dawn of the reevaluation that Cryoablation under certain conditions may obviate the decade's long disfiguring surgery, comes the reevaluation that killing cancer with Cryoablation (liquid nitrogen at -180 C or -300 F) may well activate the immune system to kill cancer cells elsewhere in the body. The investigation of this phenomenon is in its infancy. That said, there are some facts known. Cancers can and do escape the immune system's response, and one of the known ways to prevent this evasion is through immune checkpoint inhibitors. "Cryoablation causes cell death by necrosis induced by cold temperatures and by apoptosis in cells found in the periphery of the tumor. Cells dying from apoptosis do not stimulate T-cells. It is theorized that the intracellular contents of cells killed by necrosis stay intact. This may result in an immune response which may well kill cancer cells distant from the primary site. This is the Abscopal Effect. The trick is to enhance this effect. Preliminary investigation indicates this can be done by affecting the signals produced by the intracellular contents of the cells killed by necrosis. The intracellular contents cause mature dendritic cells, which fully activate T cell receptors.

This is so-called Signal 1. Signal 2 involves the interplay between programmed death receptor 1 (PD-1) on the T-cell and programmed death-ligand 1 (PD-L1) on the tumor cell. T-cell activation (and thus anti-body formation) is blocked if signal 2 is suppressed. Thus, the cancer cell escapes death. However, if the anti-PD1 antibody is used, that inhibiting signal is blocked, allowing activation of the T cell. Another immune checkpoint inhibitor, anti-cytotoxic T lymphocyte-associated protein 4 (CTLA-4), also has been shown to enhance the immune response" [3, 4]. Further investigation into the enhancement of immunostimulatory and immunosuppressive responses is needed to elucidate the potential of the abscopal effect fully.

The Tulip Procedure – We have used the Lavender Procedure on multiple old local recurrences, and those patients are now over five years out without evidence of re-recurrence. All the while, her body, and mind remain intact. It has been dubbed "The Tulip Procedure" because just like a tulip comes through the ground every spring, cancer does what it does, and that is, at times, recur. While treating doctors can differ on the ideal treatment for each patient, what they can't differ on is that there is a time interval (different for each patient) when a tumor is born and when it attains the capacity to metastasize. This is when the cancer is most amenable to conservative treatment, including Lavender. Likewise, with a nascent recurrence, that same time frame (different but real for each patient) comes to be. Since these patients are watched so closely, it has been our experience to re-Lavender these patients (after due consideration for alternative more standard of care procedures), and they have done well. More experience will dictate how many Tulip Procedures are feasible.

One final aspect is the psychological impact on the operating doctor. In traditional therapy, the blame for a patient not doing well could be passed around, so to speak. The surgeon did not get clear margins, the oncologist did not use the right drug, and the radiation therapist did not use the right portals. With Lavender, there is only one person to blame, and one must be able to withstand the pressure each time one of these patients undergoes mammography.

Conclusion

In the beginning, a clarion call was issued for radical change in the standard of care in the diagnosis and treatment of breast cancer. A different standard of care will be called for if The Lavender Way and Lavender Procedure have a mainstream presence. The gist of all this is that embracing Lavender, bodies, lives, and families can be saved without enormous cost, and any trained doctor could do it. A large cancer center is not needed to execute this endeavor. While there are more emerging articles about Cryoablation, we are not aware of any entity that has figured out a way to ensure the successful outcome that finding ultra-small breast cancer portends like The Lavender Way. That is the key. We all have to decide just how important women are and act on it. “Since 2005, 70 percent of approved drugs have shown zero improvements in survival rate while up to 70 percent have been actually harmful to patients.

The issue is not so much that there has been little progress in cancer research; the question is why there is so little improvement in treatment. With minor variations, a protocol of surgery, chemotherapy and radiation - the slash-poison-burn approach to treating cancer – remains unchanged. It is an embarrassment. Equally embarrassing is the arrogant denial of that embarrassment” [2]. A search of the literature reveals almost 4 million papers published on cancer. The question is who reads all these papers?? Who is in charge of implementing any change on a nationwide or global basis?

It is clear that confronted with this regimen, how will change, and a cure for cancer ever come to pass? In the United States of America, at least, only one person has the legal and moral authority to break this stranglehold on cancer research, and that is the President of the United States. Recently, the Space Force was authorized as a separate entity among the various armed forces of the U.S. The President could enact a new and separate research agency with a new vision, separate and apart from existing health agencies such as the N.I.H. and NCI.

Alternatively, a forward-thinking country could initiate The Lavender Way and Lavender Procedure and publish their results. The first country to do this will bring a new paradigm to the detection and treatment of breast cancer. Ultimately, women and their caregivers must demand this change in the standard of care. As final thoughts, it is apropos to revisit some writings of Dr. Vincent T. DeVita Jr as his experience should open our eyes to just how innovation takes place and what hinders it, especially in a disease like cancer. Taken from an article published in the New Yorker on December 7th, 2015, “The breakthroughs made at the N.C.I. in the nineteen-sixties and seventies were the product of a freewheeling intellectual climate. The social conditions that birthed a new idea in one place, impeded the spread of that same idea in another. When the cancer researcher Bernard Fisher (R.I.P.) did a study showing that there was no difference in outcome between radical mastectomies and the far less invasive lumpectomies, he called DeVita in distress. He couldn't get the study published.” This is a sterling example of people's uptight nature reluctant to change even when positive results are staring them in the face.

This example of Fisher's problem getting his study published points to another problem of American cancer researchers. What isn't mentioned in DeVita's article or in the publication of Fisher is that Fisher's trial's

initiation was based totally on Umberto Veronesi's landmark article. Simply by our American researchers embracing a well-done study by the Italians and getting this new, less disfiguring treatment out there immediately, we had to do yet another six-year-long re-do. Even when results verified Umberto's, it took about twenty years for lumpectomy to be accepted. Now with functionaries leading the way with ever-mounting regulations and insistence on ‘evidence-based medicine’ as the only way, no wonder women are continually sacrificed.

DeVita further states, “Clinical progress against a disease as wily and dimly understood as cancer, DeVita argues, happens when doctors have the freedom to try unorthodox things – and he worries we have lost sight on that fact.” Another sterling example is his association with Dr. Freireich at the N.C.I. This is how intrathecal injections of an antibiotic came to save the lives of people with leukemia and Pseudomonas Meningitis. “The first time Freireich told me to do it, I held up the vial and showed him the label, thinking that he'd possibly missed something. It said right there, Do Not Use Intrathecally. I said, Freireich glowed at me and pointed a long bony finger in my face “DO IT.” “He barked. I did it, though I was terrified. But it worked every time.” No evidence-based medicine here. Concerning breast cancer, specifically, DeVita writes, “Years ago, women with all stages of breast cancer had radical mastectomies, leaving just tissue over bone and a painful swollen arm. Then they died. Look how far we've come.” The question now is, have we come far enough to see the light, or are we reverting to 'getting it all' with oncoplastic surgery, with the simultaneous incrimination of Cryoablation and advanced non-radiation diagnostic modalities? Considering the entrenched opinions of a key self-appointed hierarchy, our assertion that the only person to break this tumult is the President of the United States – by authorizing a new research agency and deployment of a pilot study of Lavender Breast Centers.

Data Availability

Data can be received upon request that supports the conclusions of this paper.

Conflicts of Interest

None.

Consent

Informed consent was obtained from all patients.

Ethical Approval

These proceedings were carried out with ethical standards set down in the 1964 Helsinki declaration and its later amendments. No animals were used.

Competing Interests

None.

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Author Contributions

All three authors agree to the contents of this paper.

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