

Extracorporeal Shock Wave Therapy – A new “wave” (also) in Physiatry?

Prof. GELU ONOSE, MD, PHD, Univ. Assist. CRISTINA DAIA CHENDREANU, MD, POSTGRAD.,
Univ. Assist MONICA HARAS, MD, POSTGRAD., AURA SPINU, MD, POSTGRAD.,
IOANA ANDONE, MD, POSTGRAD

University of Medicine and Pharmacy “Carol Davila”, Bucharest

ABSTRACT

Shock waves are mechanical/ballistic swinging beats that need for conveying themselves, a propagation medium. The medical use of SW is actually called Extracorporeal Shock Wave Therapy (ESWT) and it is based on high-intensity sound pressure waves, generated outside the body, than can be inside focused, at a specific zone.

Key words: shock waves, sound pressure, focused

BACKGROUND

From a technological point of view, in the fifties, the first patent of an electro-hydraulic shock wave generator was accepted in the USA. In 1971, it was reported the first in vitro disintegration of a kidney stone with shock waves (SW) without direct contact to it (1).

From a biomedical point of view, the SW based therapy is at present, the method of choice for the treatment of most of the kidney and urethral stones: introduced in 1980, it has been used since, very successfully, for the disintegration of calcified deposits in Urology but in Orthopaedics, as well – starting with 1985 – as a contribution of German researchers.

So, around a half decade later, SW began to be used for the treatment of several muscle-skeletal diseases, especially throughout Europe;

yet, the first “officially” accepted indication of SW in this kind of pathology, appeared in 2000 in the USA and referred to the Food and Drug Administration (FDA) approval for its use in the therapy of plantar fasciitis (2).

In muscular-skeletal tissues, SW manifested dose-dependent actions, promoting (also) biological mechanic-transduction (Orthotripsy) (3) – different from their effect used in Urology, being much more complex (see later). □

PHYSICAL AND TECHNICAL DATA

Definition: physically, SW are mechanical/ballistic swinging beats that – unlike electromagnetic ripples – need, for conveying themselves, a (material) propagating medium.

The medical use of SW is actually (completely) called Extracorporeal Shock Wave Therapy

Adresă de corespondență:

Prof. Gelu Onose, University of Medicine and Pharmacy “Carol Davila”, No. 8 Eroilor Sanitari Bvd., Bucharest
email: geluonose@clicknet.ro

(ESWT): ESWT is based on high-intensity sound pressure waves, generated outside the body, that can be inside focused, at a specific zone.

They are characterized by high positive pressure moments (up to 150 Mega Pascals – Mpa – : over one hundred times the atmospheric pressure !) developed very rapidly: the pressure increase time to the peak is only a few nano-seconds – ns(10-9) sec -: 13-120ns; the pulse duration is about 500 ns -0,5µs (10-6 sec) – alternating with negative pressure ones (of 5-10 Mpa – Fig. 1)

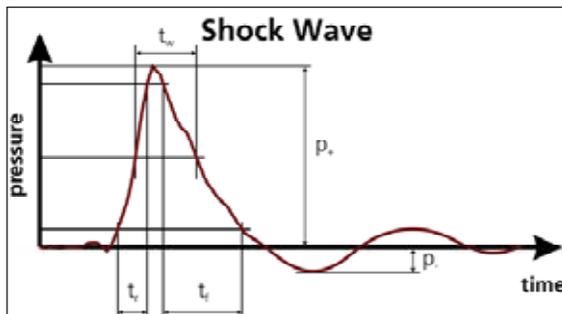


FIGURE 1. Time/pressure profile of a SW (4)

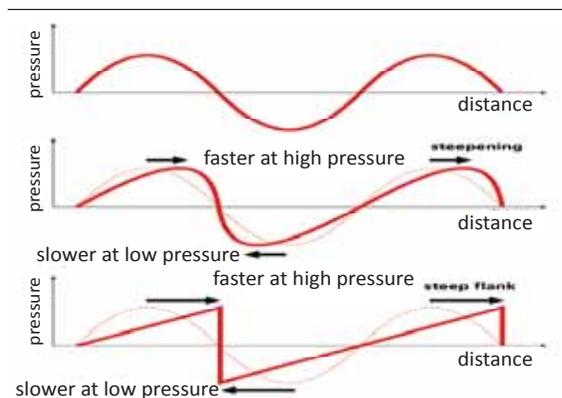


FIGURE 2. Schematic representation of the steepening of a wave front, due to non-linearity in the propagation medium; in order to form a SW front, the wave runs faster in zones with higher pressure and thereby it steepens (4)

The physical characteristics of SW interfering with targeted tissues’ biological properties – including reactivity – result in the complex and at present, still far to be known well enough, effects of ESWT.

The most related items comprising vagueness are: the type of applied energy (low versus high), the number of treatments (one versus multiple), the total number of applied shocks and respectively, the need for anesthesia or sedation.

In this part of our work, referring to physical parameters, there has to be pointed out that, differing energy outputs and inputs (conditioned including by the modalities of emitting and concentrating it – at the first focal point and the

second one), depending on different technical solutions/devices, makes it difficult to compare treatments’ effectiveness (even) for the same muscle-skeletal indications (3).

The peak value in a certain location of the SW field is plotted following the paradigm: high energy density is associated with placing it in an optimal focal point.

Accordingly, in an attempt to define the concepts of low-, medium-, and high – energy SW, Rompe and co-workers has defined low energy waves as energy density of 0.08 mJ/mm² at the second focal point, whereas an energy density up to 0.28 mJ/mm² constituted medium energy, and an energy density exceeding 0.6 mJ/mm² was considered high energy (5).

To be specified: likewise regarding most of the other ESWT parameters, by now, there is still little consensus on this subject matter.

As emphasised even from the definition, propagation of the SW needs a material medium because is based on the displacement of particles from rest position and their springing back to rest position. Consequently, the particles of the exposed medium are submitted to tough, positive and negative pressure variations; apparently paradoxical (also/mainly) the moments in which are temporally generated negative pressures have an important contribution to the destructive role of SW: the negative pressure component of the wave generate the overshoot/explosion of particles (4).



FIGURE 3. The effect of a focused SW on a cube-shaped artificial stone with an edge length of 10 mm; in the picture above, SW occur from the right and breaks up the stone, held on a wire, into a few pieces and there are cavitation bubbles in the SW path, too (4)

Technically, to produce SW, it is necessary that a kinetic energy is converted into an acoustic one; the obtaining of the respective kinetic energy is usually based on the motion and weight of a projectile accelerated by compressed air: when the projectile strikes an unmoved surface (shock transmitter) it is generated a radial or spherical SW pulse (6,7). So, SW are eventually produced through a compressed air operated complex device, entailing high-precision ballistic components within the generator/applicator.

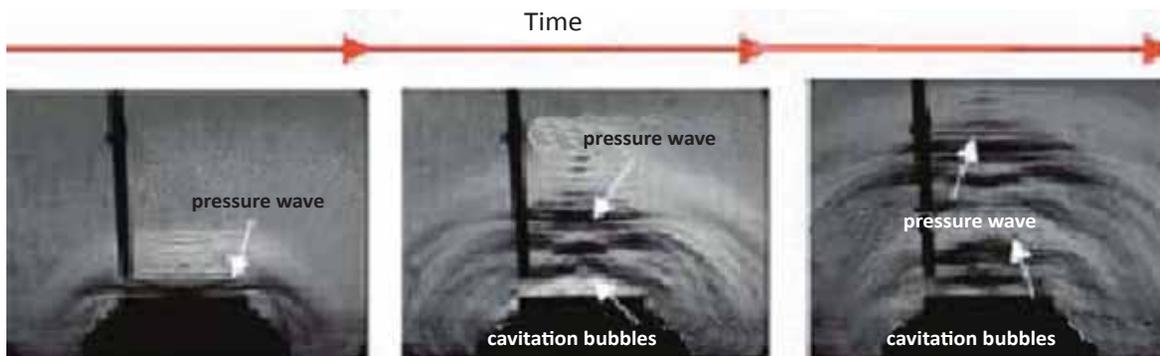


FIGURE 4. Shock wave transmission: by pressure waves and cavitation bubbles(6)

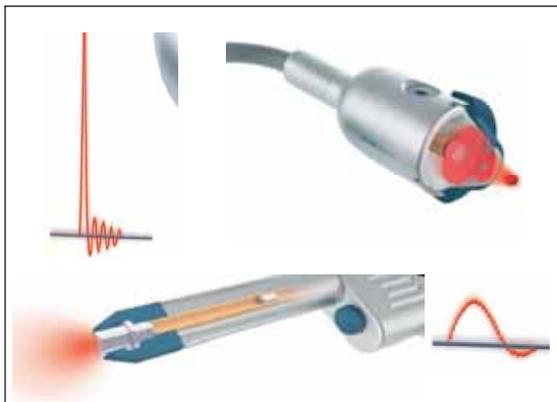


FIGURE 5. Shockwave generators: ESWT and Radial Shockwave Therapy (RSWT) (7)

To generate applicable (in living beings) ESW, there have been produced distinct electro-mechanical devices, differing from each other mainly through their physical/technical constructive solutions.

Most manufacturers use, for “somatic” applications, the same SW sources as the lithotripters, which they produce: electro-hydraulic (underwater spark discharge), electro-magnetic (flat or respectively, cylindrical membrane) and piezo-electric (8).

The technique of electro-hydraulic or “spark gap” method – the oldest, therefore so-called “historical”, one – for creating the SW: within a water-contained, stainless steel, semi-ellipsoid chamber and a contact membrane, an electrical charge ignition, produced by an electrode (spark plug) evaporates a small portion of the water and generates a SW that reflects outward off the semi-ellipsoid chamber. The spherical SW thus generated is focussed through a semi rotational ellipsoidal reflector (8). The SW generated within the reflector chamber, is through skin surface transmitted to the patient’s targeted location needing to be treated.

The electro-magnetic principle and related systems, with flat coil and lens focusing – but

better, with cylindrical coils (instead of flat ones) – associated to a reflector shaped as a rotational paraboloid, perpendicularly rotating around a standard axis of a paraboloid (9), seem to be the state of the art configuration of a SW generator: considering their technical benefits – concerning power, reproducibility, dynamic range and lifetime, including with the opportunities offered by the cylinder source to integrate in-line ultrasound or X-ray localization systems, for precise identification of the targeted structures within surrounding anatomy – they tend to become standard in high quality ESWT devices (8,9).

For practical clinical applications, there is needed to be applied a coupling solution for the contact membrane and the patient’s skin: in order to increase (mechanic) conductivity (10), to propel ESW into the body without significant losses, newer ESWT devices use such coupling cushions instead of an open water bath (8). Hence, the ballistic pulses are introduced into the body over a skin surface area through a protective cap or gel and by means of a freely moved applicator (6).



FIGURE 6. Examples of ESWT devices (11, 12)

Aside the basic physical properties of ESW, the intimate interaction (see later) and subsequently its biological/medical effects, are conditioned by the modalities of energy

generation and concentration, through different technical solutions, adopted within ESWT specific devices (Fig. 6).

Especially for soft tissues, the necessitated/ enough energy level is medium or even low; accordingly, it is not mandatory neither a very precise focalization nor a large depth (both, expensive to be technically achieved and often entailing associated imagery, too) for “classic” ESWT (6).

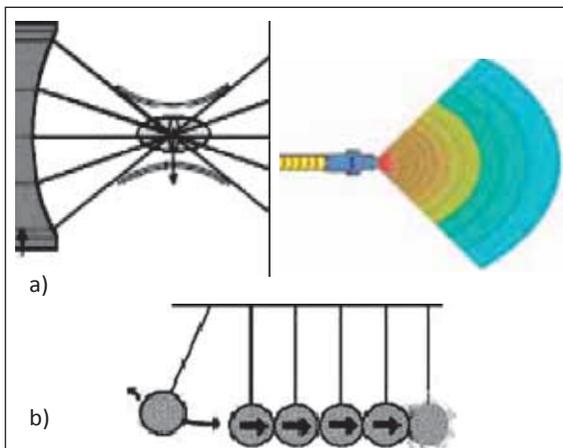


FIGURE 7. a) Focalised (conic/sharply emitted) energy; b) Radial (spherically emitted) energy (6)



FIGURE 8. ESWT/ PSWT – focused/planar shock wave therapy (13)



FIGURE 9. RSWT – radial shock wave therapy (13)



FIGURE 10. CT scan of the gluteus minimus region: penetration depths of focus (left), compared to radial (right), SW applicators (11)

There is no direct connection between the press (in Bars or MPa) and the energy, generated by a SW device, as this depends, more complexly, on the type of the material used, of the technological solutions adopted, design of the components, etc. Hence, in a synthetic, tabular form, below are shown such technical differences, with some of their distinct consequences from clinical point of view Table 1. □

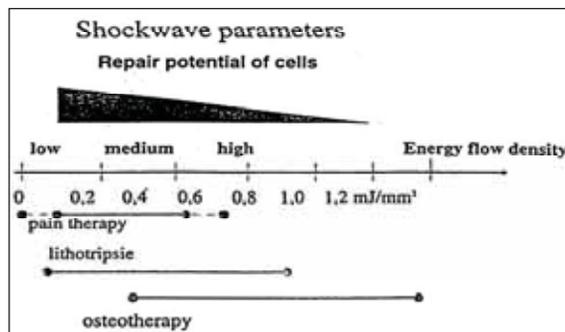


FIGURE 11. Synopsis of the relations between ESW flux energy applied and its main actions (Rompe cited by (6))

BIOLOGICAL INTERACTIONS AND THERAPEUTIC EFFECTS

In living entities, cavitation bubbles constitution, determined by SW, near/ in contact with obstacles (that belong including to intrinsic tissue’s structure)/ particles of the material

TABLE 1. Technical differences between focused, planar and radial SW, with some of the related bio-medical consequences (4)

	Shock waves (focused)	Shock waves (planar)	Pressure waves (radial)
Focus	yes	no	no
Rise time	typically 0.01 μs	typically 0.01 μs	typically 50 μs
Compression pulse duration	approx. 0.3 μs	approx. 0.3 μs	approx. 200 – 2000 μs
Positive peak pressure	0-100 MPa	0-3 MPa	0.10 MPa
Energy flux density	0-15 mJ/mm ² in the body	0.-14 mJ/mm ² at skin surface	0-0.3 mJ/mm ² at skin surface
Therapeutic effect in body	0-12 cm	0-5.5 cm	0-3 cm

medium, cannot collapse in a spherically, symmetrical way, since obstacles hamper the fluid flow.

This causes the development of micro jets that hit the interfaces at a speed of several hundred metres/sec. and leads to erosions or punch needle-like holes in biological membranes and/or vessels (4).

The discovery that ESW applications produced important responses at the infra-cellular level, changed the concept on their actions, from pure physical/ mechanical implications, to profound action mechanisms in tissues, including – seeming mainly – induction of neovascularisation, associated with/based on increased expression of angiogenic growth factors (Vascular Endothelial Growth Factor – VEGF) and also of Proliferating Cell Nuclear Antigen (PCNA), respectively of (enzyme) Nitrous Oxide Systems (eNOS), etc. (14,15,16).

ESWT's improvement to the micro-circulation in tissues, also consists in mechanically stimulating the intrinsic movements of the smallest terminal vessels in the micro-vascular system: an elementary characteristic of micro-angiodynamics – allowing the blood flow through the vascular bed to be regulated (17).

Thus, the ESWT- induced (micro) traumatic/ therapeutic eu-stress response causes blood vessel formation and consequently, increases delivery of nutrients to the affected area, too.

All these correlate with a transient increase in "shot" cells' membrane permeability – without causing (directly) cell death – based on a specific (afore exposed) process of erosion or punch needle-like holes, in membranes and/or vessels. Furthermore, in the small cavities created by the pulses, new-formed blood vessels within a surrounding area of tissue, in virtuous circle, would promote regeneration/healing.

Preliminary results of recent studies in animal models, also showed that high-energy SW might be associated with the release, as afore mentioned, including of NO free radicals and subsequently in cell apoptosis. As regarding skeletal structures, this can (differently) alter Dickkopf (DKK)-1 and respectively, Wntless (Wnt) 3a molecules (DKK-1 is a gene that inhibits the activity of osteoblasts, acting by suppression of Wnt signalling; Wnt is essential for the growth and development of osteoblasts, for cell-to-cell signalling in embryogenesis, being also implicated in cancer). Hence, ESWT increasing in PCNA and Wnt 3 and decreasing in DKK1, significantly promotes bone remodelling and regeneration (14).

At the same time, it was speculated that SW, stimulating e-NOS, with associated release of NO derived free radicals (ONOO-) and consequent cell energetics interference, might thus also be involved in the signal transduction and respectively, mediation of ESWT actions at intracellular level, for instance in their anti-inflammatory/resorbative effect on proliferative enthesites. More precisely, ESW, at a low energy density value, induced a rapid increase of neuronal nitric oxide synthase (nNOS) activity and NO neoproduction, including in neural malignancies (glioma). Thus, ESWT, proved to down regulate NF- κ B activation and NF- κ B-dependent gene expression, including inducible NOS and TNF- α (18).

Another effect of the SW seems to be a distortion of axonal contents, straining of the cell membrane, and a resulting increase in permeability, leading to depolarization, factors that effect mechano-sensibility(3) (orthotripsy – as afore mentioned).

Additionally, ESWT has also been demonstrated to increase the thickness of the reticular dermis and decrease the protrusion of fat into it (Schultz cited by 19).

As for the heart tissue, ESWT proved to beneficially influence both, differentiation and maturation of cardiomyocytes, endothelial and smooth muscle cells, and respectively, at least in animal studies – as already emphasized – it induced apoptosis in heart fibroblasts, thus reducing their number, possibly also due to the up and down regulation/modulation of growth factor production and release, mainly by acting on their auto- and para-crine components of activity. These effects seem to be significantly more obvious on normal heart cells; consequently the use of ESWT is to be recommended especially in the early stages, for instance of heart failure (20). Additionally, ESWT has been shown to increase capillary density and regional myocardial blood flow in animal experiments but also to induce non-enzymatic nitric oxide production and the up-regulation of vascular growth factor's mRNA and respectively to relieve symptoms and improve ischaemic threshold in patients with chronic stable angina pectoris (21).

An important action of ESWT is on pain and is based on complex/subtle mechanisms and related effects. In this respect, the key sub-layer is considered, at present, the "pain associative memory" concept. A modern vision on pain perception and sensation emphasizes a holographic model of it: the nervous systems would,

accordingly, generate and recall memory contents. Thus, ESWT would action upon reorganization of pathologically stored information related to chronic pain, making possible lasting relief of it. Moreover, as already exposed, the complex action of ESWT subsequently expands to some reflex based main reactive processes to pain (22, 23).

Hence, according to the afore mentioned reflex reactions to pain, afferent algogenic signals are transmitted and stored (see above), conditioning as a learning process, through the central nervous system, by multiple synaptic junctions and eventually, cause efferent fibres to control including muscle tone (23).

Within the reflex based relationship between pain and muscle tone, apparently paradoxically, but subtle, the association between pain and striated muscle and/or vascular tonus can be used to modulate it – through a beneficial disorganization of the physiological/cybernetic type, program for the reactive to pain processes, resembling to Leduc electric currents based "secunden" therapy (24) – by the stronger pain signals during ESWT.

The complexity and profoundness of SWs' intimate effects, from the gene-molecular transcriptional level to modulations within cell cycle's functioning and respectively, to the nutritional-circulating/reparative tissue one, especially in this decade, appeared – aside the already mentioned enthesopathic and kidney/urethral lithiase pathology – a significant enhancement of their clinical indications' spectra.

Hence, many new indications of ESWT, other than musculoskeletal disorders, including – as presented in another work of ours, too (25) – neuropatic hypertonia (26,27) have widely opened up the field of ESWT in clinical applications/indications (see further). □

DATA REGARDING THE METHODOLOGY OF USE

ESWT is a conservative/non-invasive procedure possibly to be administrated on outpatients too, mainly in daily sessions, lasting each a few minutes up to 30 minutes (28).

As afore mentioned, differing from patient to patient's sensitivity threshold to pain, targeted region and/or degree of pain generated by the affected area to be treated, the subject might need local and/or sedation anaesthesia.

Anyway, as a general methodological rule, he/she should be positioned with the affected zone on the machine, possibly interposing on a

soft, water filled membrane or coupling cushion.

Previously, an optimal approach could entail, if possible, an ultrasound mediated imagery of the region.

Because of the physical mechanism of the SW generation, the "shots" applied through ESWT produce a repetitive clicking of which the subject should be informed.

Another general rule, concerning the methodology of administration, refers to the cumulative energy of SW within a therapy session: the total energy applied is obtained through multiplication by the number of pulses – generally hundreds or thousands, depending mainly on the treated condition (4).

As previously mentioned, another aspect which belongs to variable areas in the related literature is the need for anesthesia or sedation (3): by even the way they emit and concentrate energy to ballistic mechanical pulses, SW inevitably will micro-traumatise tissues and thus generate, especially in more sensitive zones, pain of variable degrees. But, corroborated with the subtle and complex deep intra tissue modification, the fast and strong specific SW action upon pain receptive structures, can also result in its efficient modulation.

Although the side effects reported by now are rather few and not severe, there are still some – anyway abating in 3 to 7 days – that worth to be mentioned: mild increase of pain, haematomas, skin irritations/(including subcutaneous) tumefaction(6), tingling or numbness, bruising/floating sensations and/or swelling or even rupture of the plantar fascia and damage to the blood vessels or nerves. □

INDICATIONS

Aside for the neuro-myo-artho-kinetic "apparatus" related pathology indications (presented in a previous work of ours (25)) herein below, we reproduce only some of the newer ones (still to be confirmed in practice and respectively in more consistent literature):

- osteonecrosis/aseptic bone necrosis, osteochondritis dissecans, osteomyelitis, periostitis, non-union/pseudarthrosis (6,28);
- skin lesions including infected wounds/topical antibacterial applications, burns, plastic flaps/reconstructions, venous/arterial/decubitus ulcers, esthetic dermatology (anti-cellulite/biolysis) (19);

- stable chronic angina pectoris, ischemia induced myocardial dysfunction (21);
- spasticity (26) including in children with cerebral palsy (24, 29);
- sports – including lymphatic drainage effect in the treatment of sports injuries (chronic shoulder or back pain as well as ankle and knee joint pain – are including volleyball ailments) (30). □

CONTRAINDICATIONS

- pregnancy (6,31)
- children in growth – on metaphyseal areas and/or ossification nuclei (6)
- tumour diseases, especially malign ones (31)
- acute inflammation/pus focus in the target area (6)
- thrombosis/phlebitis (6)
- coagulation disorders (haemophilia) (6, 31)
- use of anticoagulants (6)
- prolonged cortisone therapy (6)
- non-cooperative patients (for instance, with dementia) (6)

Situations and/or locations to be avoided/considered: patients with conditions that lead to poor tissue quality – such as fibromyalgia – and irritable bowel syndrome (tend to be less responsive to ESWT) (32) and/or fragile tissues, anatomic locations for nerve structures and/or big blood vessels, organs containing air filled cavities (lungs, bowels), an unprecise and non-palpable pain area, growth cartilage(s), vertebrae – especially the cervical ones –, the heart region (? – o.n.), an open scar within the area to be treated (6). □

DISCUSSION

As pointed out in (25) there are many unsettled issues that the International Society for Musculoskeletal Shock Wave Therapy (ISMST) must play a role to resolve them. Aside the summing, of them in (25), we add here one more item: in clinical application, SW should be recommended as one of the initial choices of treatment for acute and chronic insertional tendinopathies rather than only for chronic refractory conditions of 6 months or longer duration (33). This comes as a further development of the growing recognition of ESWT's beneficial effects in musculoskeletal pathology (actually the only morbid entities for which ESWT has already been approved by FDA, are radial and/or ulnar humeral epicondylitis and calcaneal spur/plantar fasciitis; regarding the latter, it is actually the method of choice for the patients whose heel pain has not resolved with classical conservative treatment: anti-inflammatory medications – including local steroid injections –, cryotherapy, slow stretching – even through orthoses – and electro and/or photo-therapy). □

CONCLUSION

As resulting from this, to our knowledge, first review in the Romanian literature, regarding main data on SW/ESWT, although not anymore belonging to a new domain, its modulator actions and related: applying methodology, indications and contra-indications – especially in the somatic/neuro-mio-arthro-kinetic structures – represents an expending field of research and clinical applications with promising prospective, but also with still enough unknown issues, including few citable references, needing to be further explored. □

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REVISTA PRESEI MEDICALE INTERNAȚIONALE

Simple life changes could stop millions of cancers

About a third of all common cancers in the United States, China and Britain could be prevented each year if people ate healthier food, drank less alcohol and exercised more, health experts said on Friday.

Estimates from the American Institute for Cancer Research (AICR) and the World Cancer Research Fund (WCRF) suggest that making simple lifestyle changes could prevent some 40 percent of breast cancers alone in Britain and the United States, as well as tens of thousands of colon, stomach and prostate cancers.

“It is distressing that even in 2011, people are dying unnecessarily from cancers that could be prevented through maintaining a healthy weight, diet, physical activity and other lifestyle factors,” Martin Wiseman, a WCRF medical and scientific adviser, said in statement.

In China, 620,000 cases, or 27 percent are preventable, the WCRF said, as are about 35 percent, or 340,000, in the United States and 37 percent in Britain. Healthier lifestyles could prevent 61,000 cancers in Brazil and 79,000 in Britain.

The WCRF findings are backed by World Health Organisation (WHO) re-

commendations, which say regular exercise can prevent many diseases such as cancers, heart diseases and diabetes.

Cancer is a leading cause of death around the world and its incidence is rising. Each year around 12.7 million people discover they have cancer and 7.6 million people die from some form of the disease. There are about 200 known types of cancer.

According to the International Agency for Research on Cancer (IARC), cancer will kill more than 13.2 million people a year by 2030, almost double the number it killed in 2008 – and the vast majority of deaths will be in poorer countries.

In a separate statement, the Geneva-based WHO said low levels of physical activity are the main cause of an estimated 21 to 25 percent of breast and colon cancers, 27 percent of diabetes cases and 30 percent of heart disease cases worldwide.

Rachel Thompson, the WCRF’s deputy head of science, said that while the message was simple – that not smoking, eating good food and being a healthy weight can help ward off many cancers – it was still a difficult one to get across. “It’s all very well us saying ‘this is what you

need to eat and this is how much physical activity you need to do’, but we need to make it easier for people to make those changes,” she said. “Everybody has a role in that – from international organizations, to governments, to people themselves.”

The WHO says adults should do at least 150 minutes of moderate exercise a week. This could be done by walking for 30 minutes five times per week or by cycling to work every day.

Peter Baldini, head of the World Lung Foundation, also called on all governments to introduce smoke-free laws and raise the price of cigarettes.

Tobacco kills millions of smokers every year, and tobacco-related lung cancers also kill hundreds of thousands of people who don’t smoke but have been exposed to it second-hand.

“There isn’t a magic bullet to cure all forms of cancer, but we have the opportunity and the obligation to protect people from developing cancer wherever possible,” Baldini said.

editing by Matthew Jones
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